Safer and More Affordable

–

Clinical and Business Imperatives Aligned

Ed Weisbart, MD, CPE
Chief Medical Officer

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Betsy Lehman

Boston Globe Health Reporter

"Celebrity illness can help change public attitudes.

There is no shortage of precedents."

Boston Globe, May 23, 1994

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How Could This Have Happened?

Let’s take a quiz…

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Paris in the the Spring

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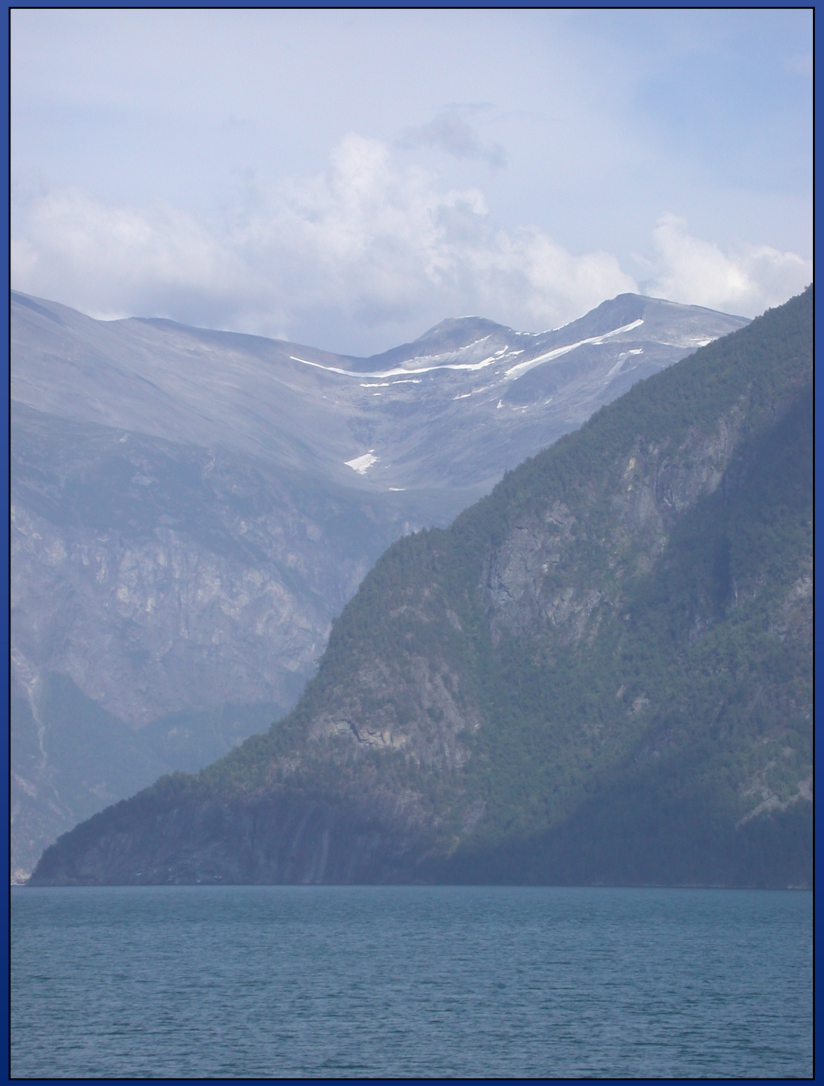
How big is this problem ?



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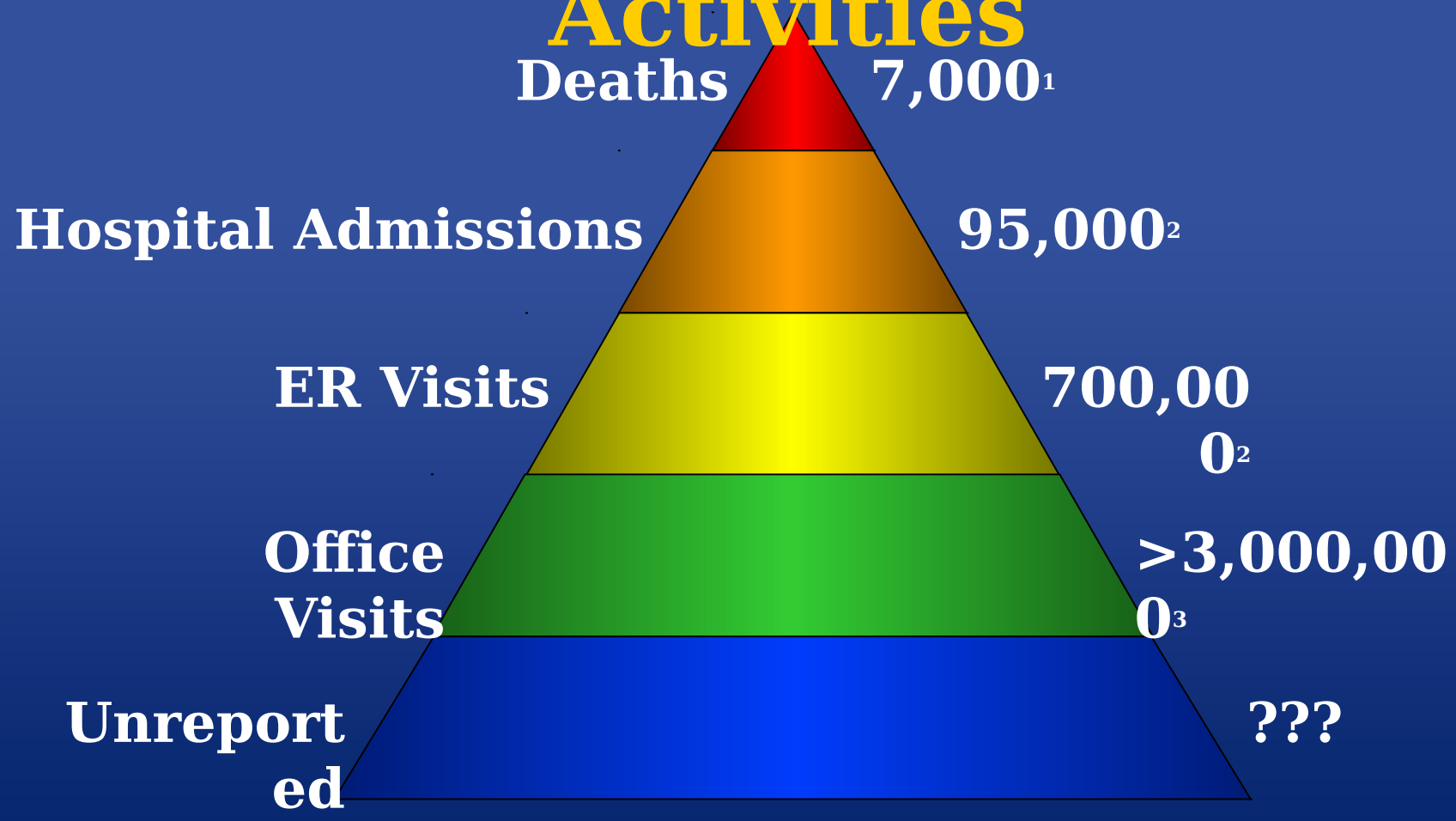
Estimated US Annual ADE Activities



1: *To Err Is Human*, 2000
2: Preliminary NEISS-CADES estimates at IOM July 6, 2005
3. Joint Commission Journal on Quality and Patient Safety. 2005;31:372-378

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Clinical and business imperatives aligned…

5th most common cause of death:
All ADEs combined[3]

15th most common cause of death:
NSAID GI ADEs[2]

1 out of 3 hospitalizations for GI bleeding:
NSAIDs[1]

1. Lanas, A. *Am Jnl Gastroenterology*; August 2005
2. Wolfe, MM. *NEJM* 1999; 340:1888-1899
3. Lazarou et al, JAMA. 1998; 279:1200-1205

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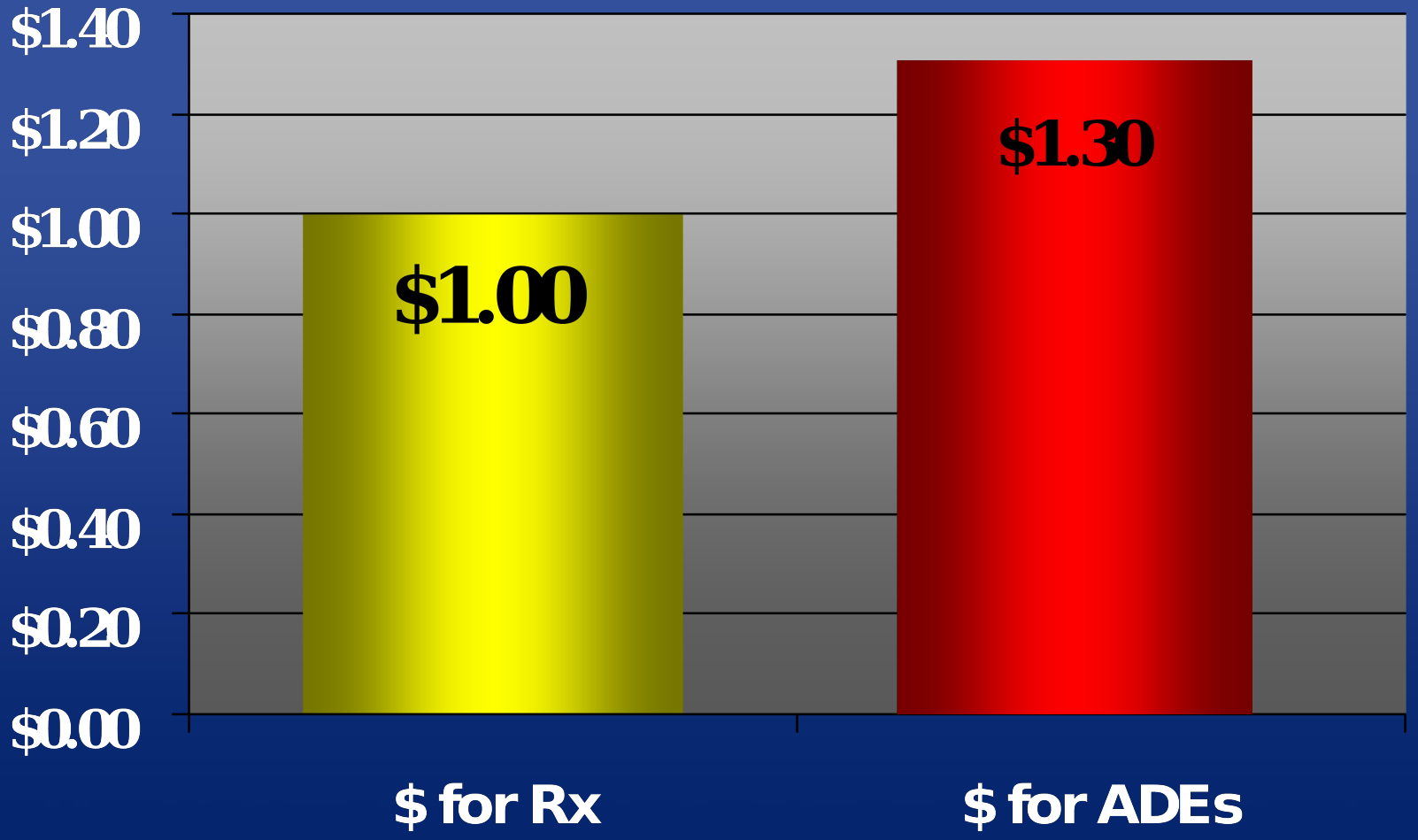
ADEs Cost More Than the Drugs!



Ernst, Grizzle. *J Am Pharm Assoc*. 2001

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Can We Do Anything About This?

Adverse Drug Events Overall:

- more than 25% preventable

Life-threatening or fatal ADEs:

- **more than 50% preventable**

Gurwitz, JH. *JAMA* 2003; 289:1107-1117.

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Improving Safety: Step One

See The Problem

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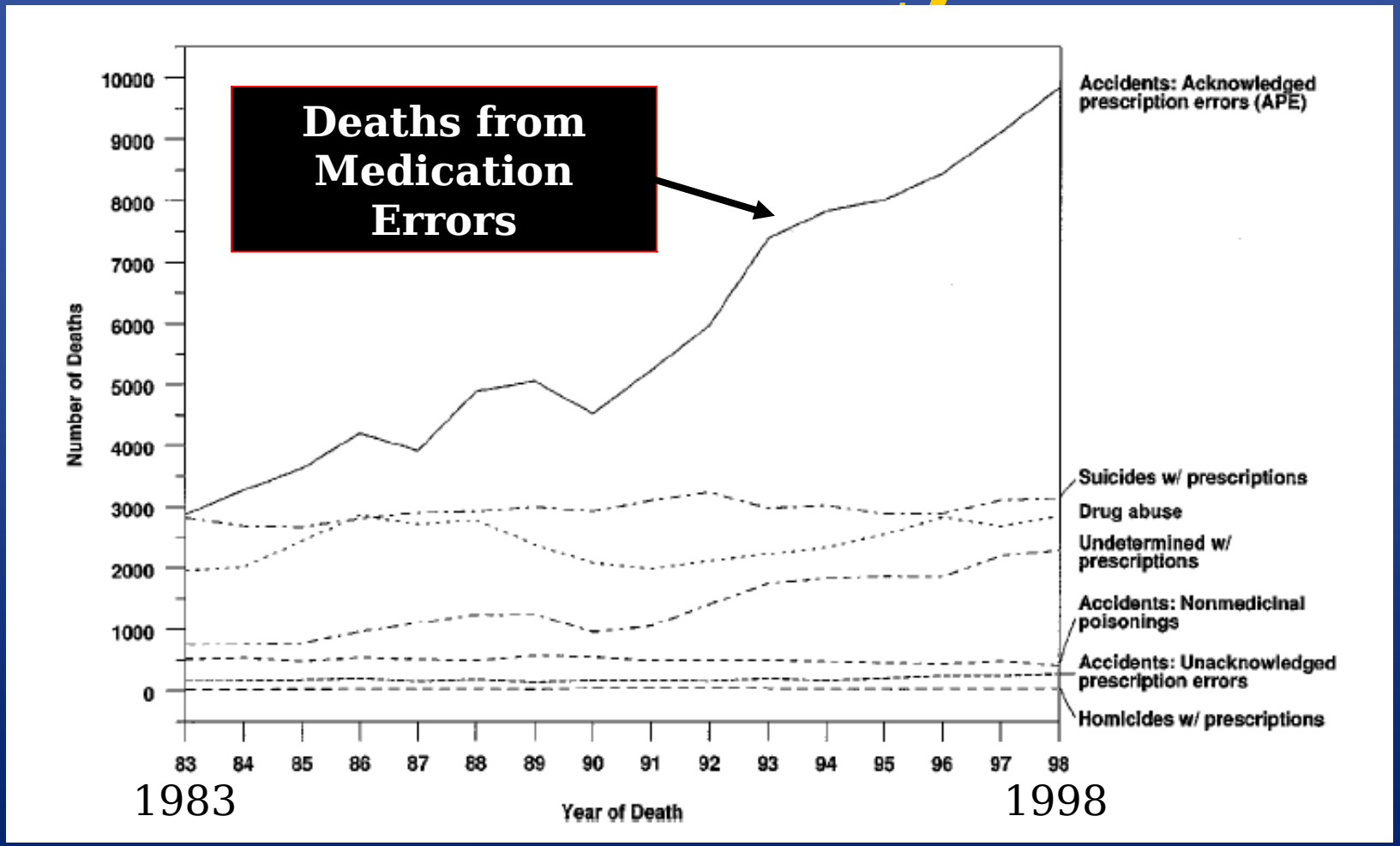
Medication Error Deaths *Increasing*



Phillips DP. *Annu Rev Public Health*. 2002;23:135-50.

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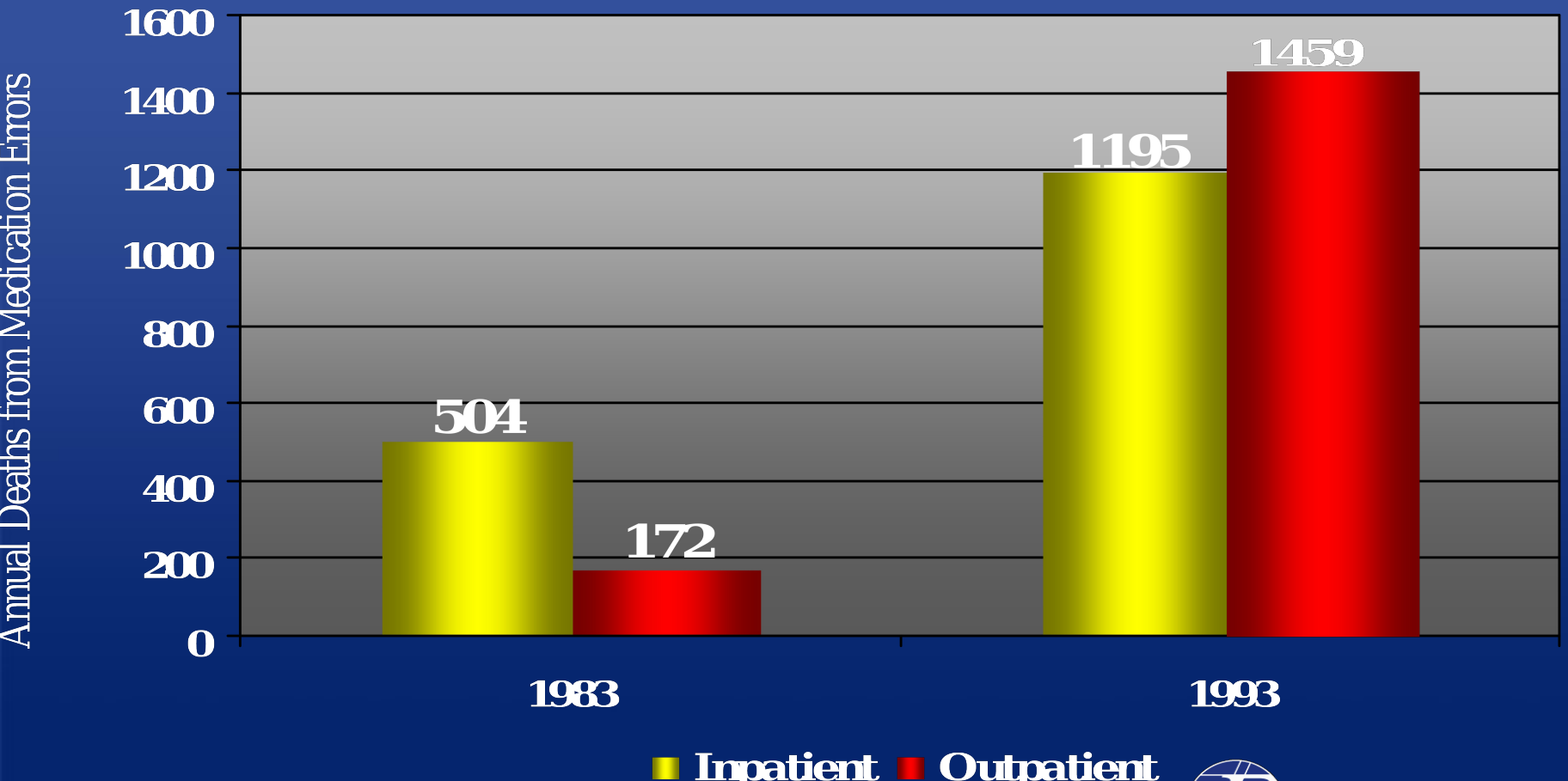
US Medication Error Deaths:

Shifting from Hospitals to Outpatients



Phillips. *Lancet*, Feb 28, 1998. 351:632

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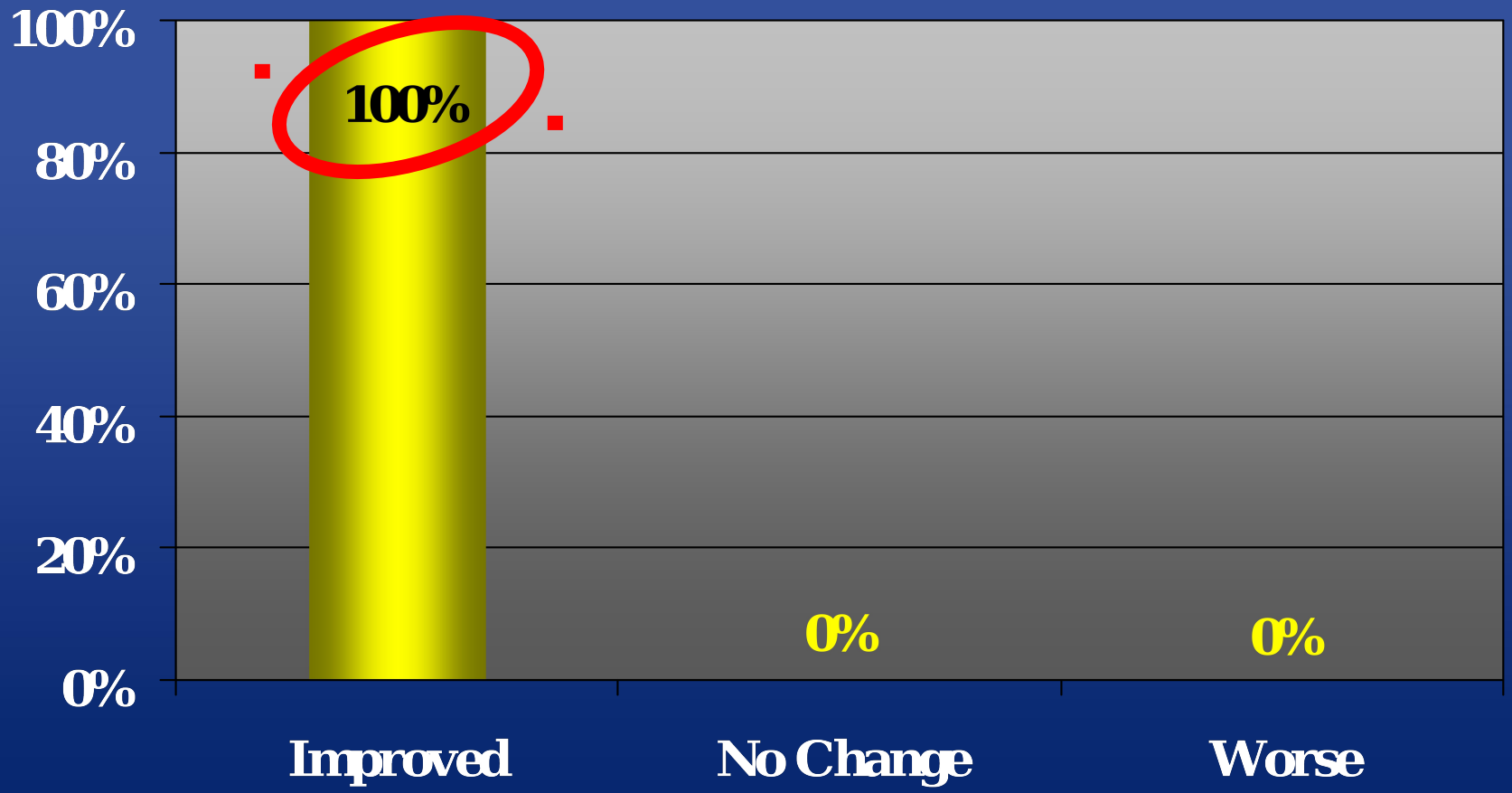
Antihypertensive Drug Therapy and Quality of Life:

Physician's Assessment



Jachuck et al; *Jn of the Royal College Gen Pract.* 1982 Feb;32(235):103-5

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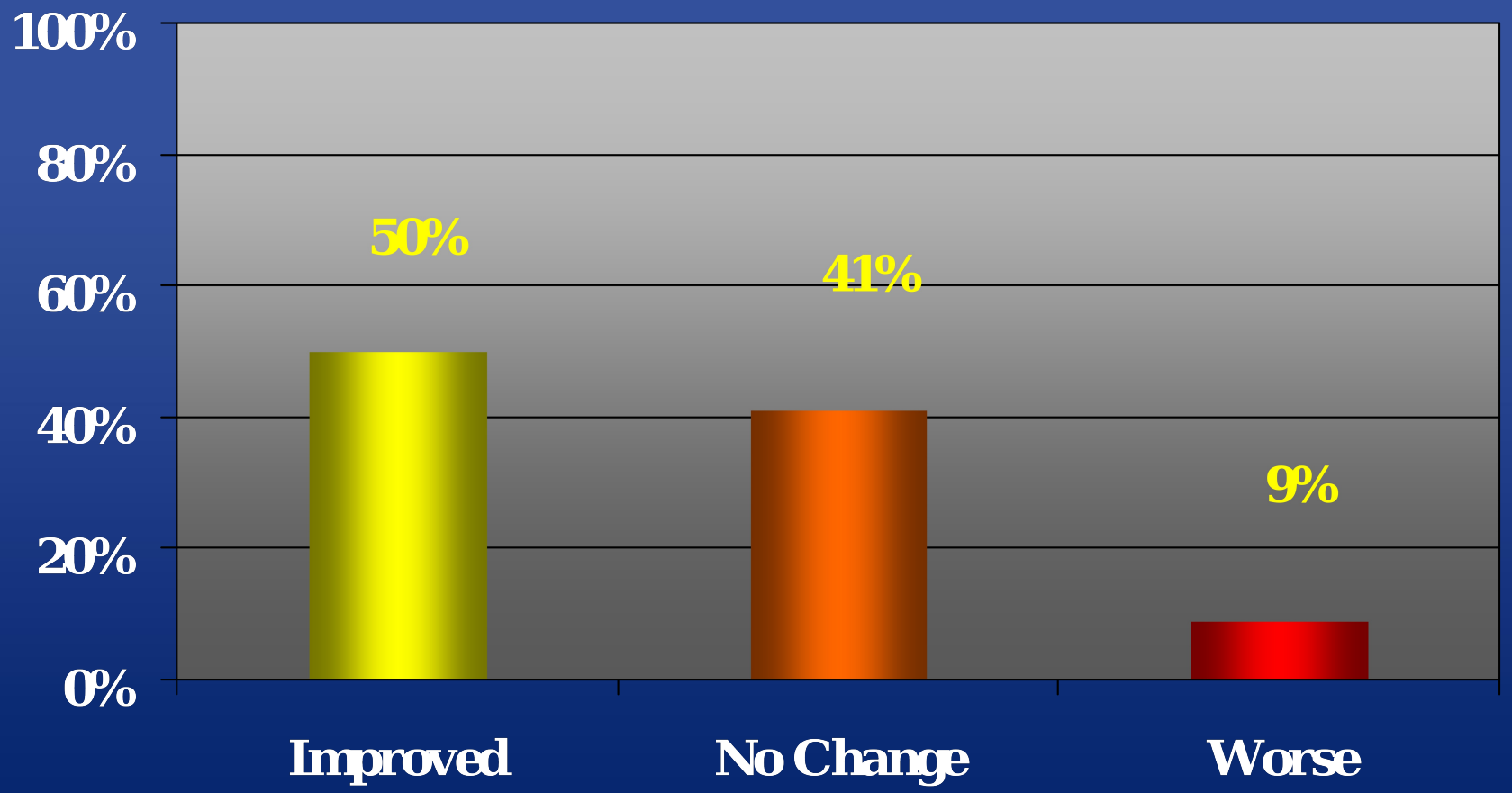
Antihypertensive Drug Therapy and Quality of Life:

Physician's Assessment



Jachuck et al; *Jn of the Royal College Gen Pract.* 1982 Feb;32(235):103-5

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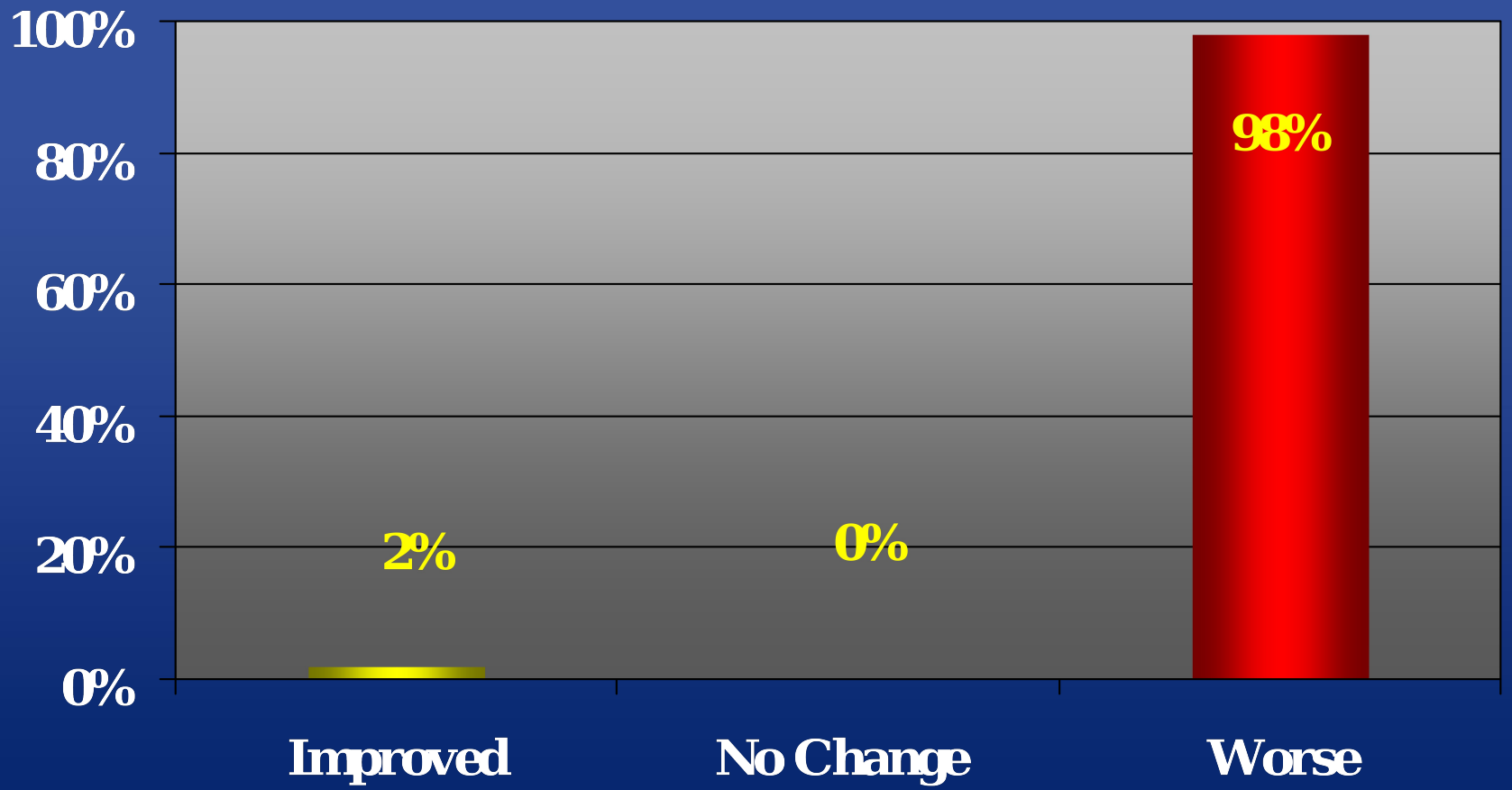
Antihypertensive Drug Therapy and Quality of Life:

Relative's Assessment



Jachuck et al; *Jn of the Royal College Gen Pract.* 1982 Feb;32(235):103-5

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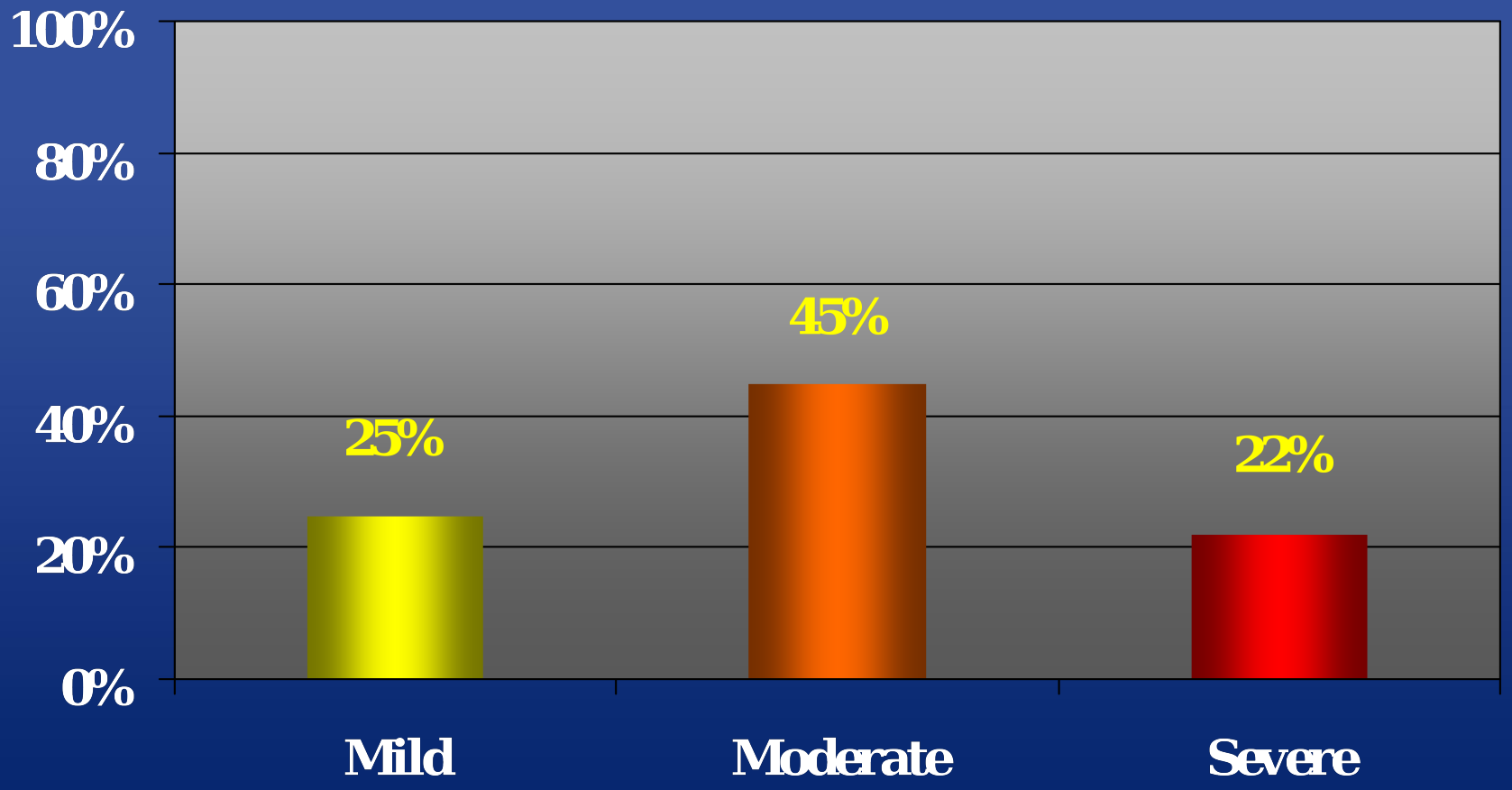
Antihypertensive Drug Therapy and Quality of Life:

Relative's Assessment of Adverse Changes



Jachuck et al; *Jn of the Royal College Gen Pract.* 1982 Feb;32(235):103-5

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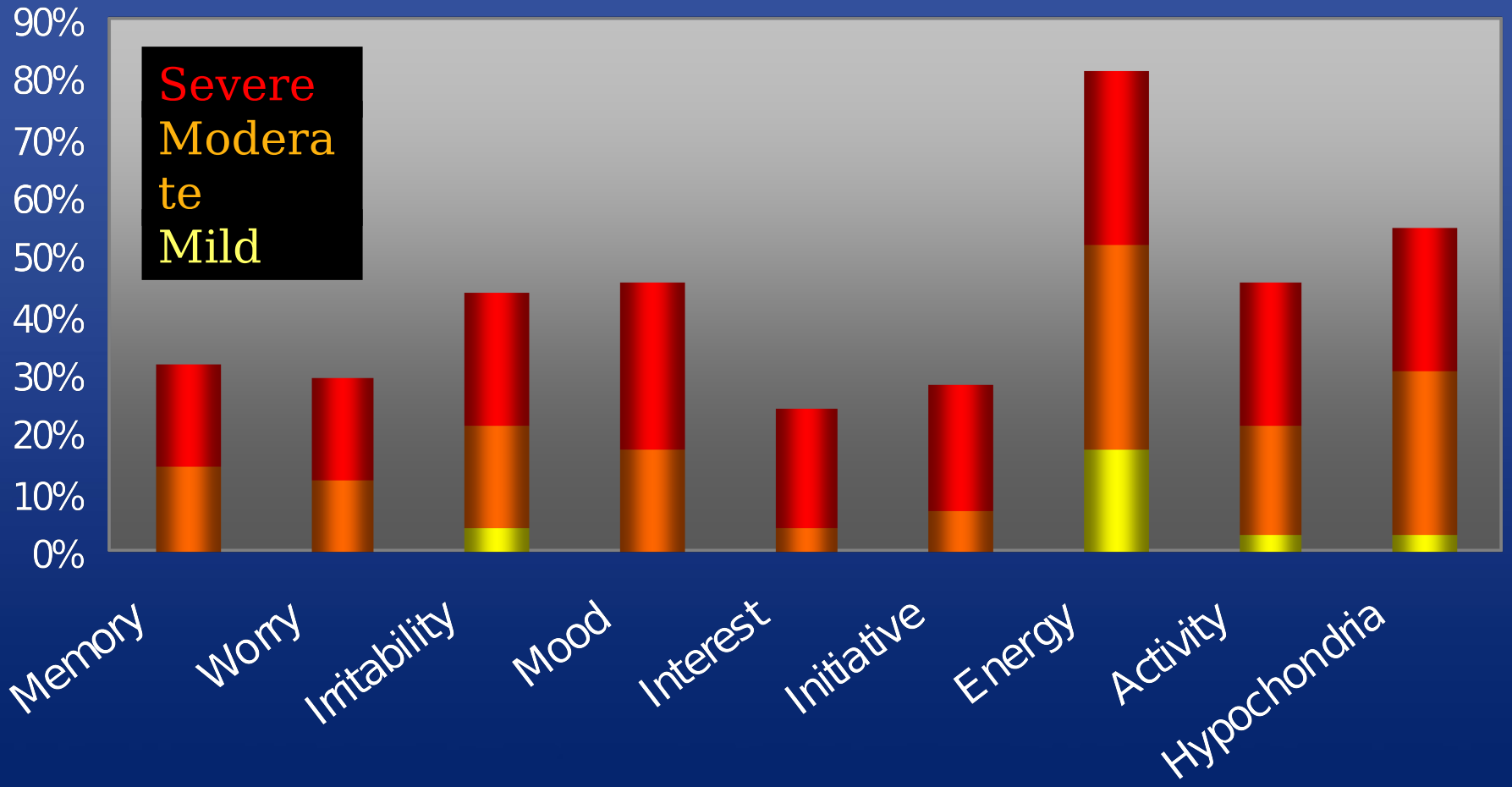
Antihypertensive Drug Therapy and Quality of Life:

Relative's Assessment of Adverse Changes



Jachuck et al; *Jn of the Royal College Gen Pract.* 1982 Feb;32(235):103-5

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How Many Could *You* Remember?

1979: 60 drugs
2006: 300 drugs

Drug-Drug Interactions (DDIs) increase *exponentially* with these numbers

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Micromedix lists more than

100,000

potential Drug-Drug Interactions.

So somebody teaches this to medical students, right?

Langdorf et al. *Acad Emerg Med* 2000; 7:1321-1329

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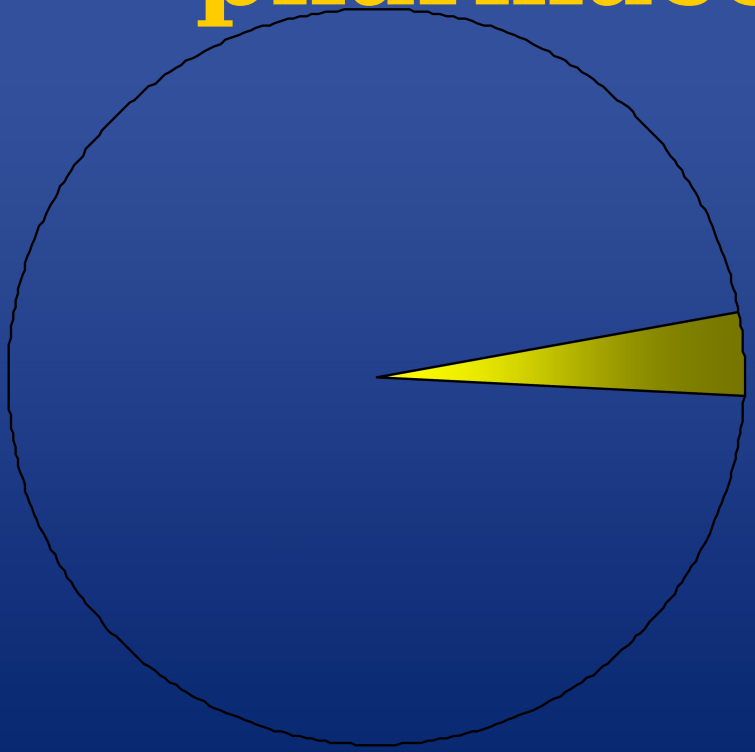
How many US medical schools require clinical pharmacology?



Less than 4%

Rosebraugh, C. Centers for Education and Research on Therapeutics Report. *Clinical Pharmacol Ther* 2002;71:4-10

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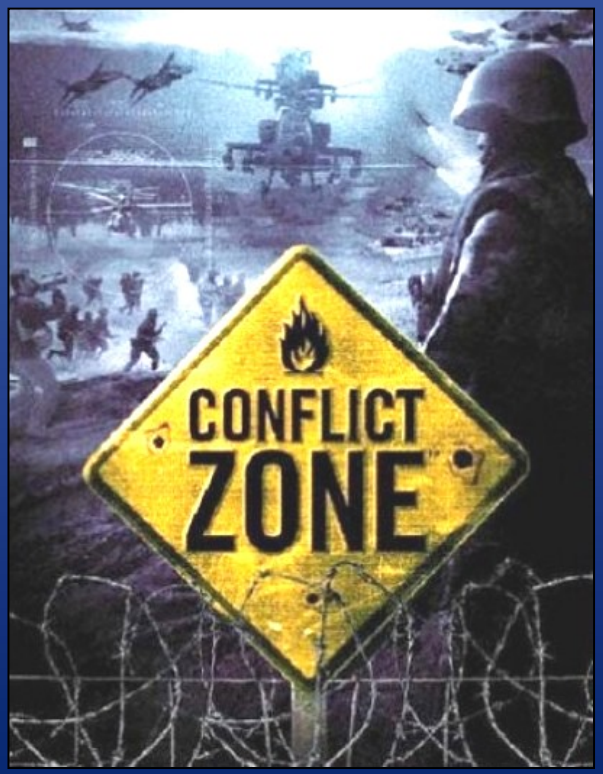
Case Study:

Terfenadine and ketoconazole

- Lethal interaction
- Published in *JAMA*

Combined use continued for 8 more years.



Monahan, B; *JAMA*, Dec 1990; 264: 2788 - 2790.

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"Asking an individual doctor

to rely on his memory is like

asking travel agents to

memorize airlin schedules."

Berwick, D. Escape Fire, 2002. pg. 47

DEPARTURES
Airline/Flt. No. Destination
Gate Time Remarks
JAPAN AIR. 061 NARITA 103 2:00P DEPARTED
AMERICAN 7211 NARITA 103 2:00P DEPARTED
LAN CHILE 601 LIMA-B. AIRES 115 2:10P DEPARTED
AMERICAN 7709 LIMA-B. AIRES 115 2:10P DEPARTED
THAI AIR 773 NARITA-BANGKOK 110 2:30P BOARDING
ASIANA 201 INCHON 121 2:30P BOARDING
UNITED 4661 INCHON 121 2:30P BOARDING
VARIG 8839 SAO PAULO-RIO DE JA 119 2:45P
AERO CALIF 133 DURANGO-TORREON 123B 2:50P BOARDING
SINGAPORE 011 NARITA-SINGAPORE 102 2:50P BOARDING
LUFTHANSA 457 FRANKFURT 104 2:55P BOARDING
SWISS 041 ZURICH 106 3:10P
AMERICAN 6211 ZURICH 106 3:10P
AIR FRANCE 065 PARIS 120 3:30P
CHINA AIR. 005 TAIPEI 122 3:55P
AIR PACIFIC 811 NADI 109 4:10P
AERO CALIF 147 LORETO-LA PAZ-GUAD. 123B 4:15P
TAHITI NUI 021 PAPEETE 105 4:20P
MEXICANA 905 MEXICO CITY 123 4:30P
LUFTHANSA 453 MUNICH 101 4:40P

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Improving Safety: Step Two

Identify The Risk

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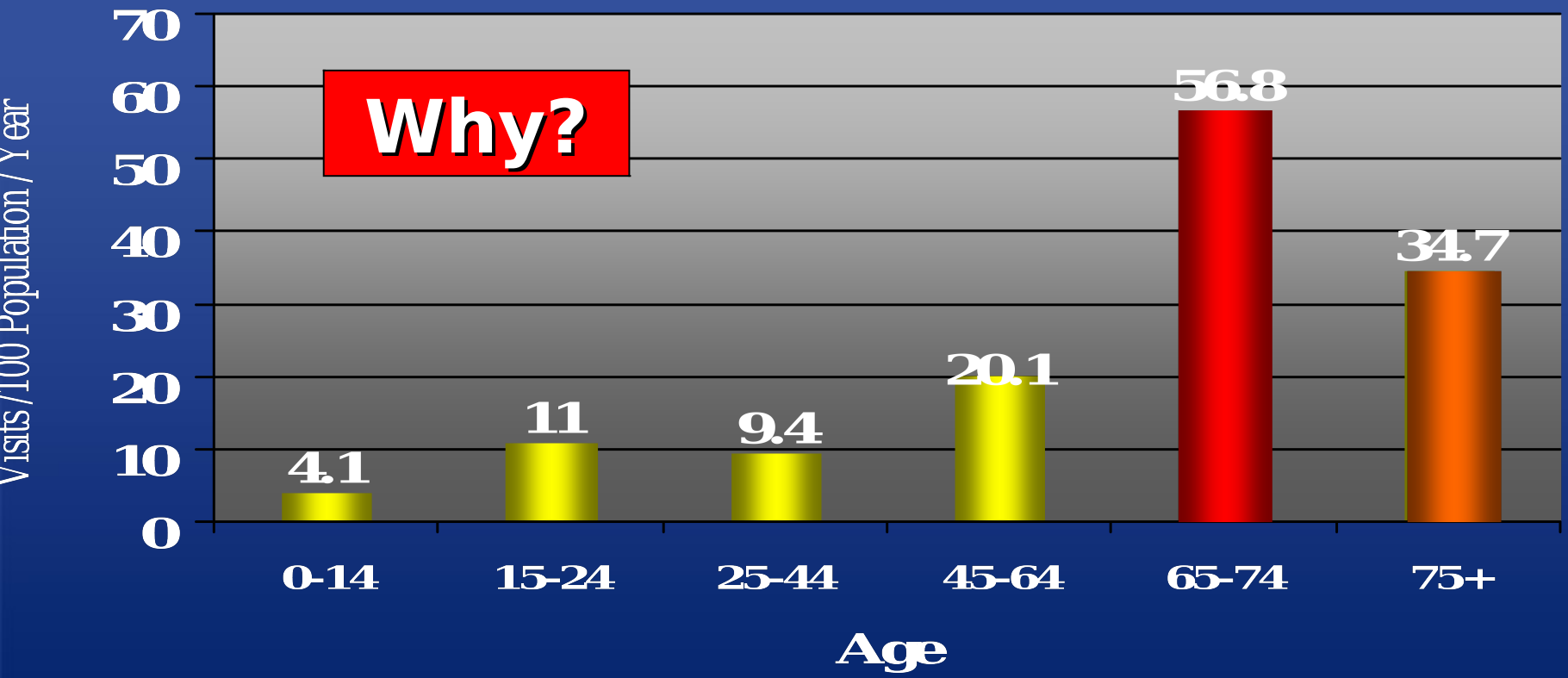
Office Visits For ADEs Increase With Age



Zhan C. *Jt Com Jnl on Quality and Pt Safety*. 2005;31:372-378.

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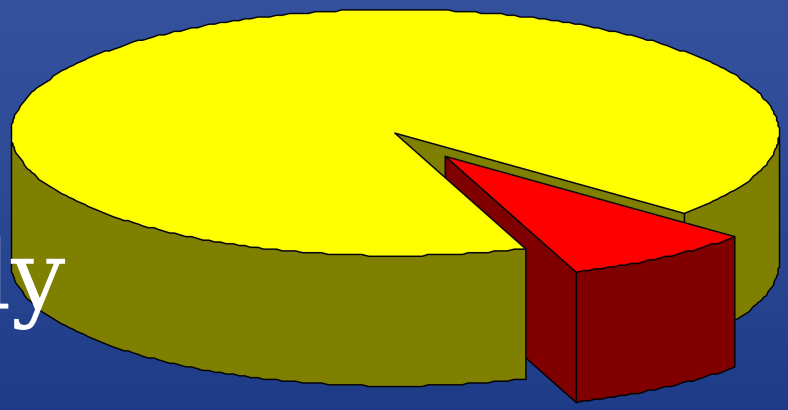
One in twelve physician visits for the elderly ends with a potentially unsafe drug.



Goulding. *Arch Intern Med*. 2004;164:305-312

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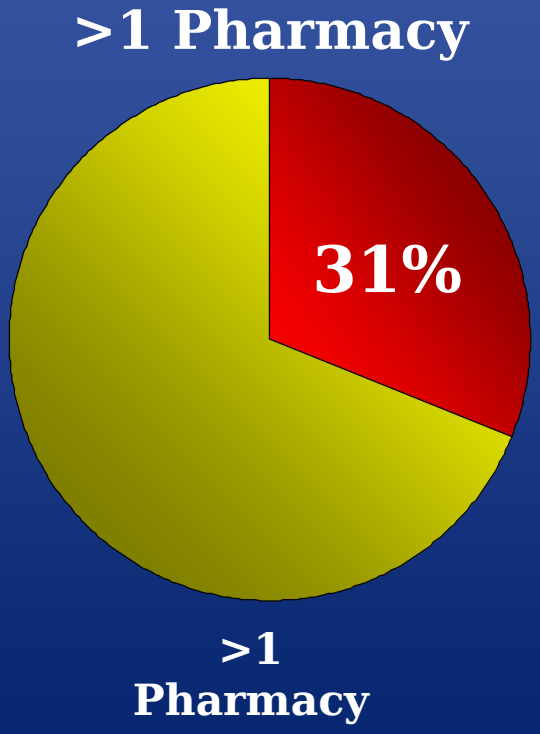
31% Of Seniors Use More Than 1 Pharmacy



Challenge:

Comprehensive medication history for drug interactions

Safran, D. *Health Affairs*, W5-152-166. April 19, 2005

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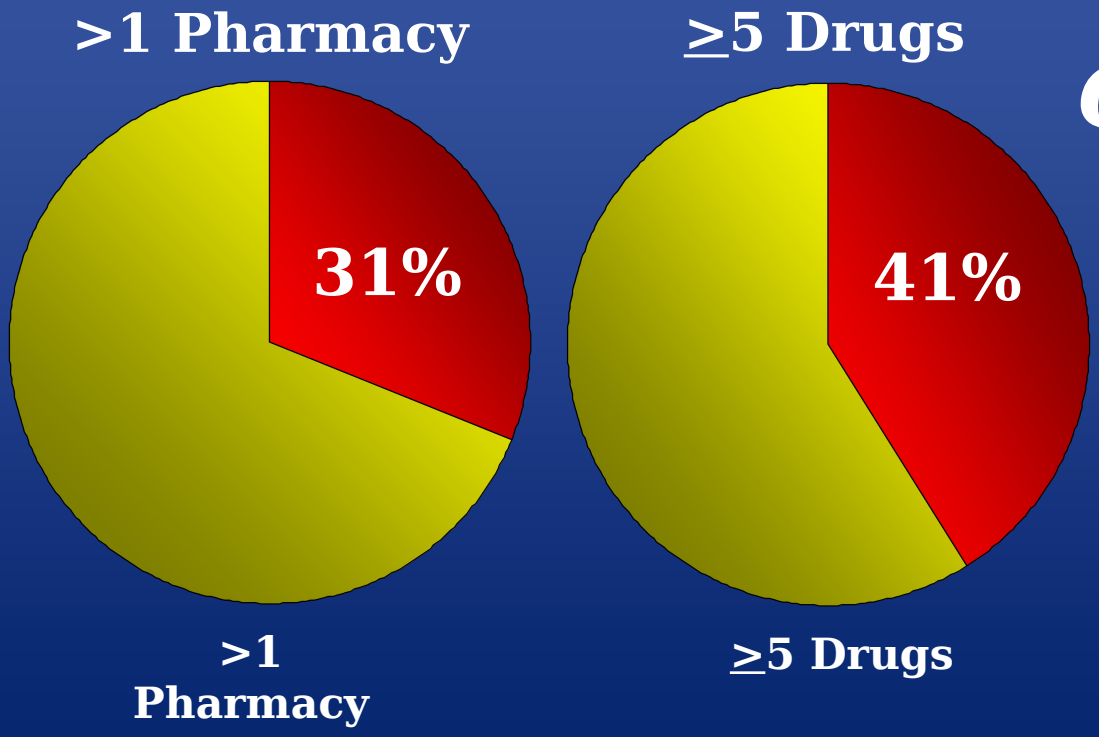
41% Of Seniors Take 5 Or More Drugs



Challenge:

Polypharmacy is a major risk factor

Safran, D. *Health Affairs*, W5-152-166. April 19, 2005

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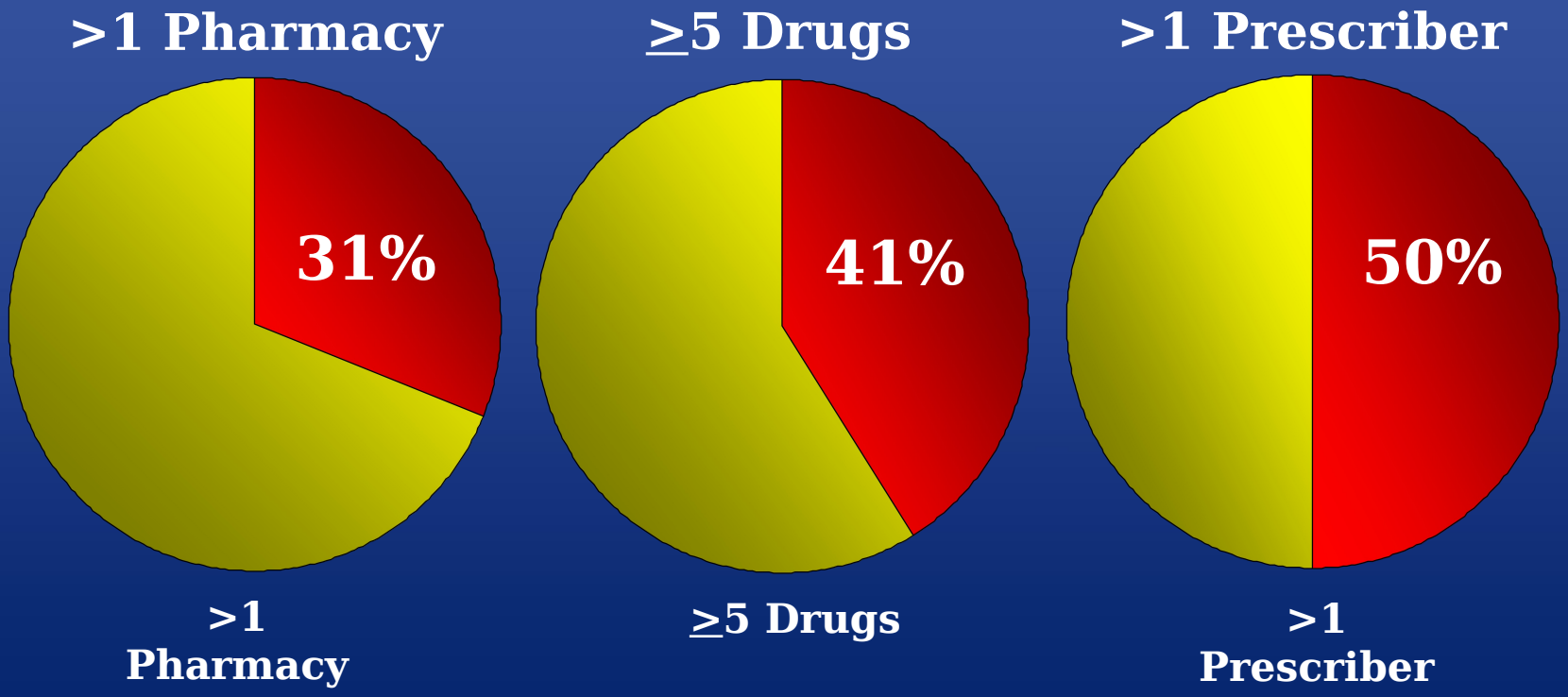
50% of Seniors Get Rxs From More Than One Prescriber



Safran, D. *Health Affairs*, W5-152-166. April 19, 2005

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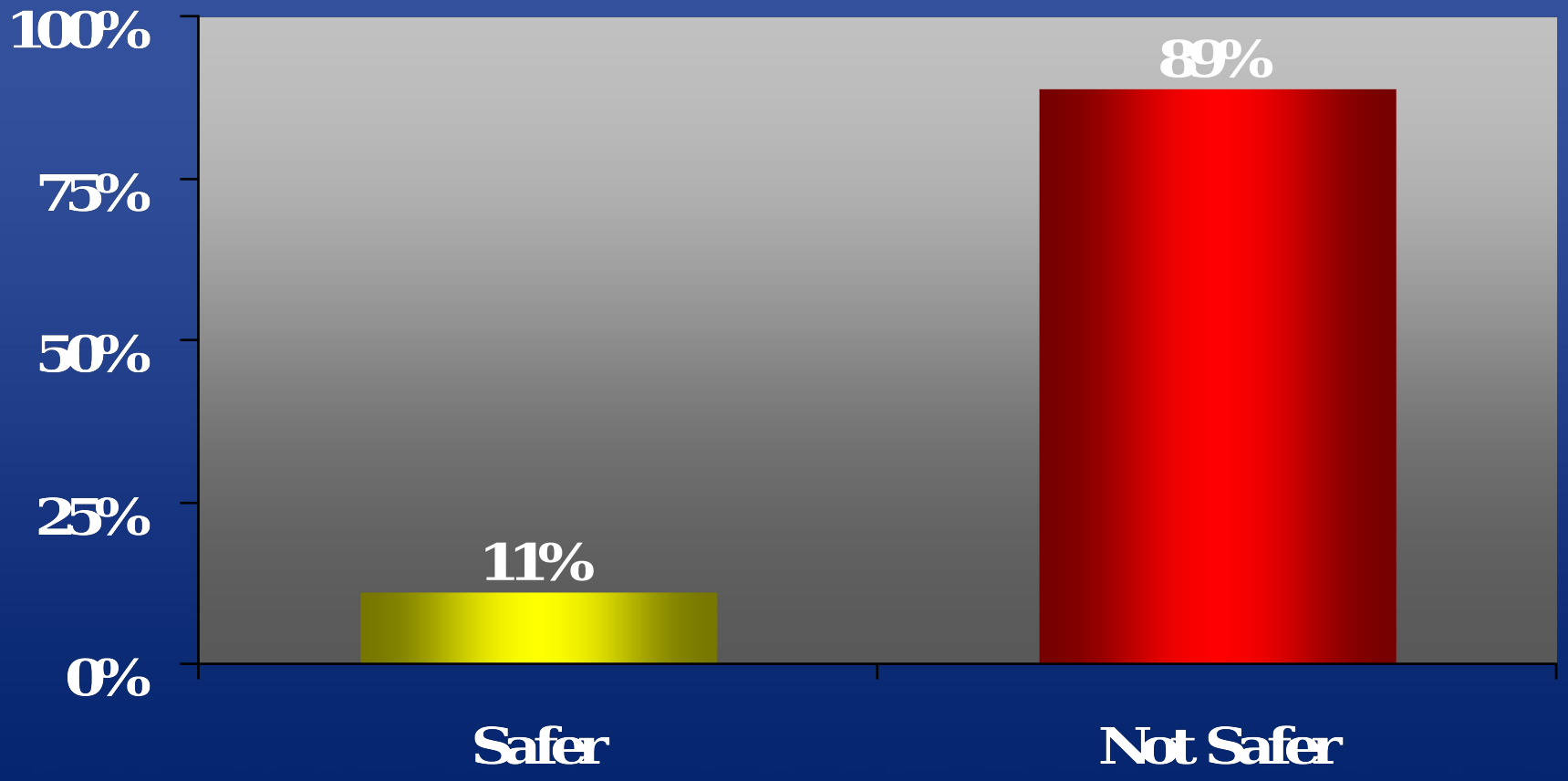
Older Americans Doubt The Safety Of Newer Drugs…



Carlson,L. *Employee Benefit News*, July 2005.

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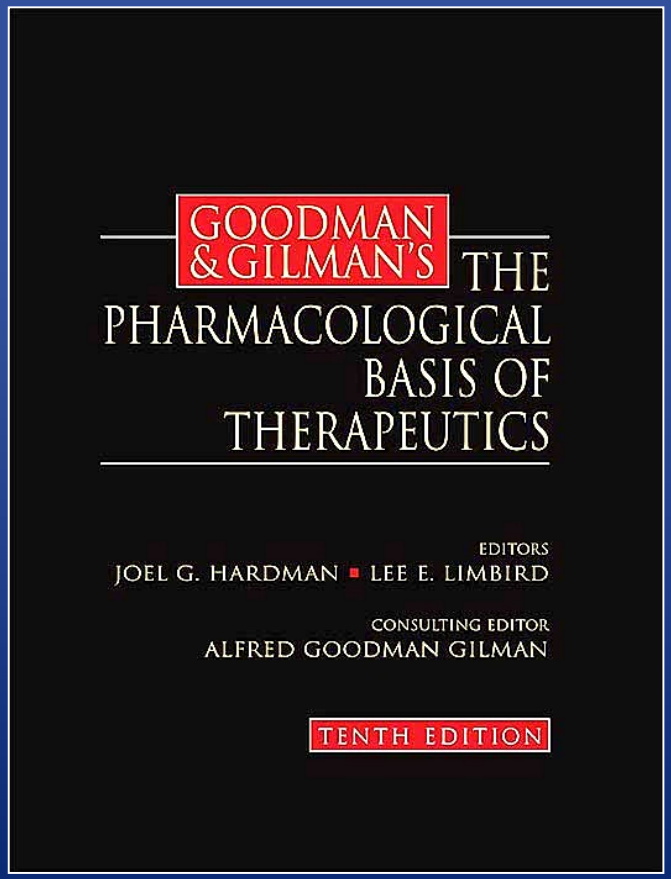
…As Do Medical Textbooks.

"New drugs are inherently more risky because of the relatively small amount of data about their effects."



Goodman and Gilman, *The Pharmacological Basis of Therapeutics*, 2001. pg. 59

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10 Years, 16 “Unsafe” Brand Drugs

- 1996: Trancopal
- 1997: Fen-Fen
- 1998: [illegible]
- 1998: [illegible]
- 1999: [illegible]
- 1999: RotaShield
- 1999: Hismanal
- 1999: Trovan
- 2000: Rezulin
- 2000: Propulsid
- [illegible]*
- 2005: Tysabri
- 2005: Bextra
- 2005: Palladone

Two generic drugs withdrawn for safety in 20+ years

* Reintroduced with new safety program

Source: FDA Medwatch

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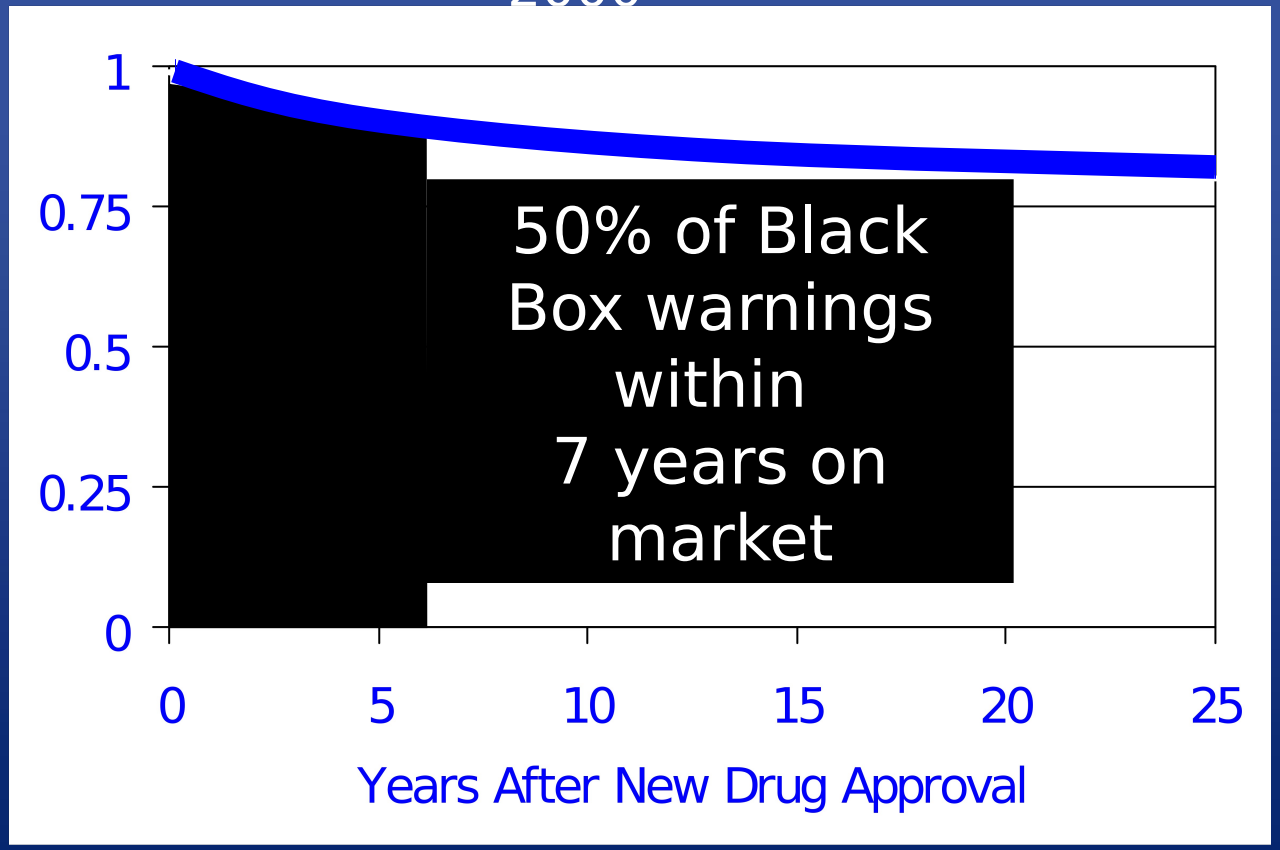
Patent Expiration Predicts Safety

All new US drugs, 1975-2000



Lasser, K. E. et al. JAMA 2002;287:2215-2220.

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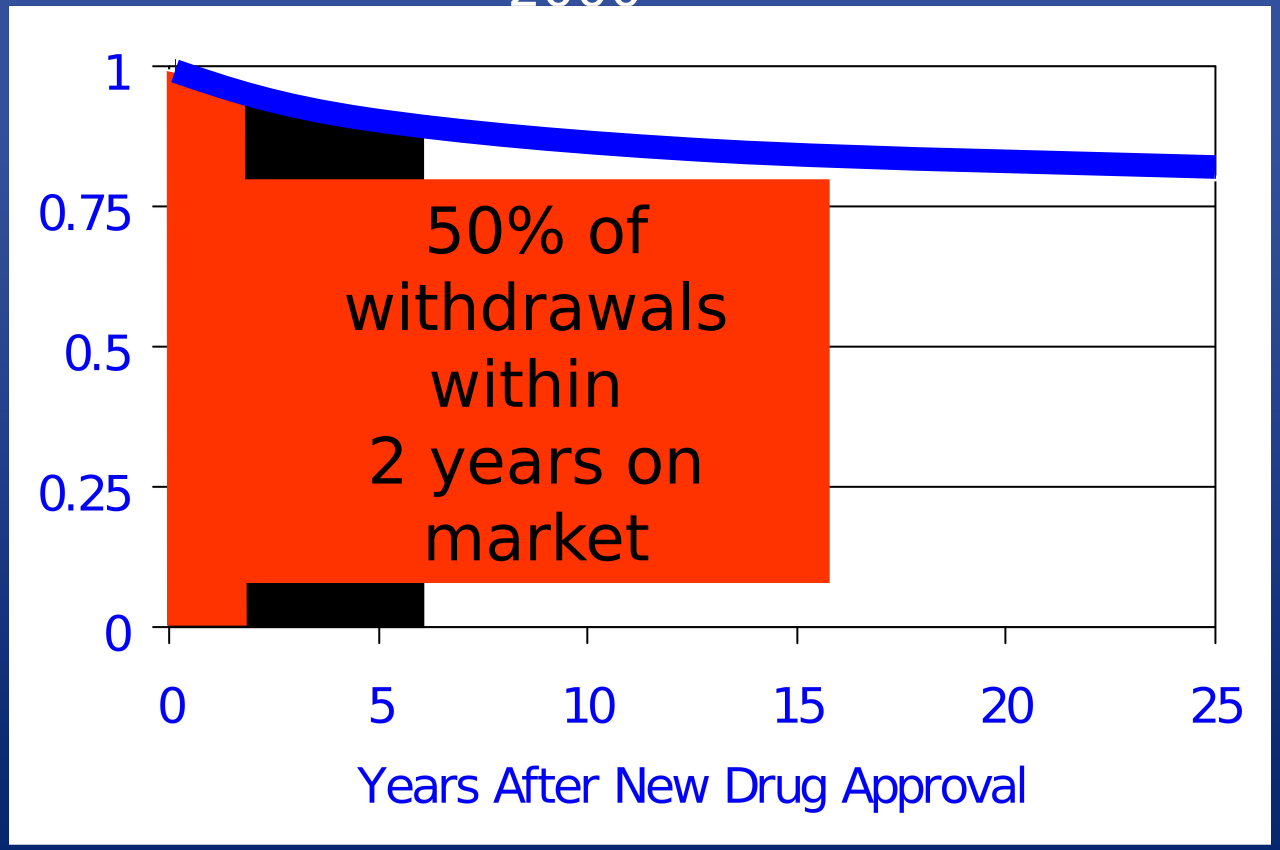
Patent Expiration Predicts Safety

All new US drugs, 1975-2000



Lasser, K. E. et al. JAMA 2002;287:2215-2220.

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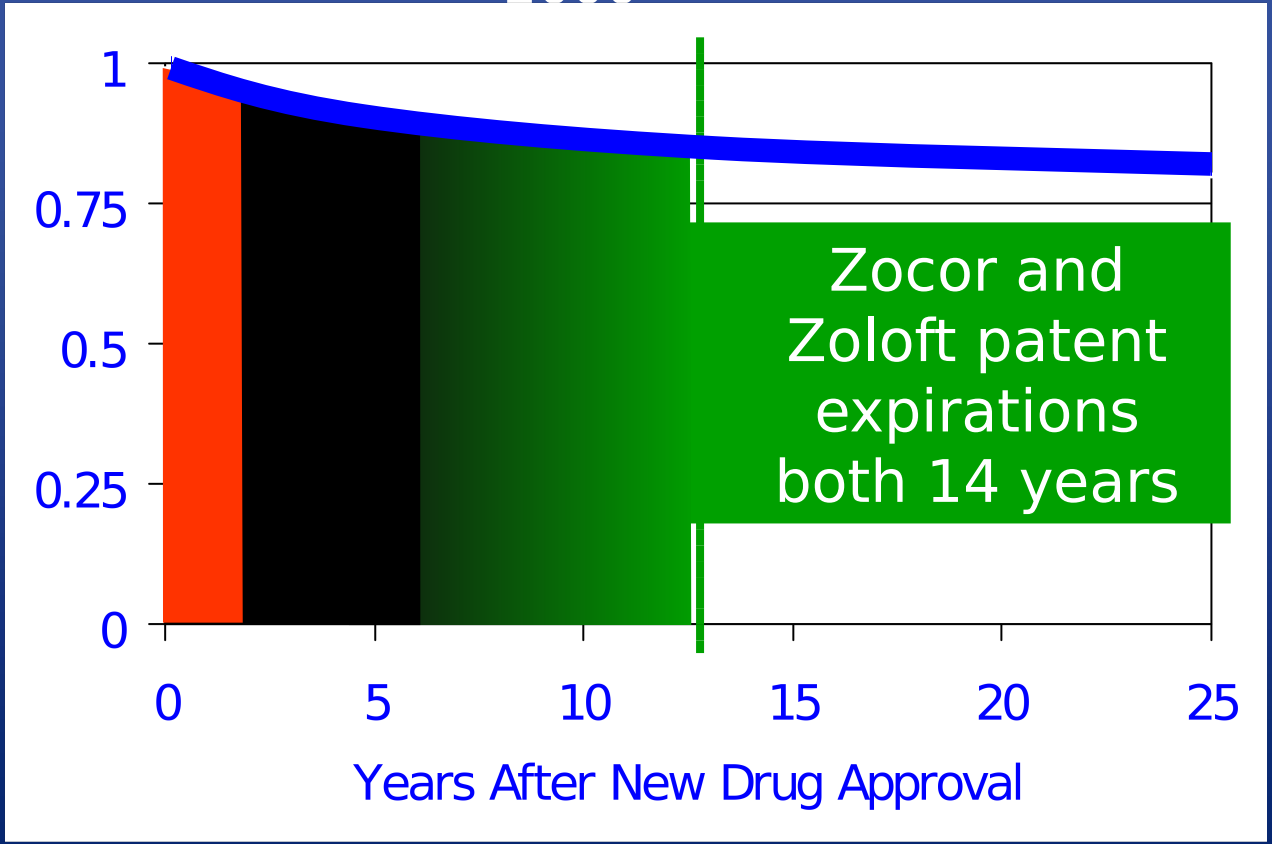

Lasser, K. E. et al. JAMA 2002;287:2215-2220.

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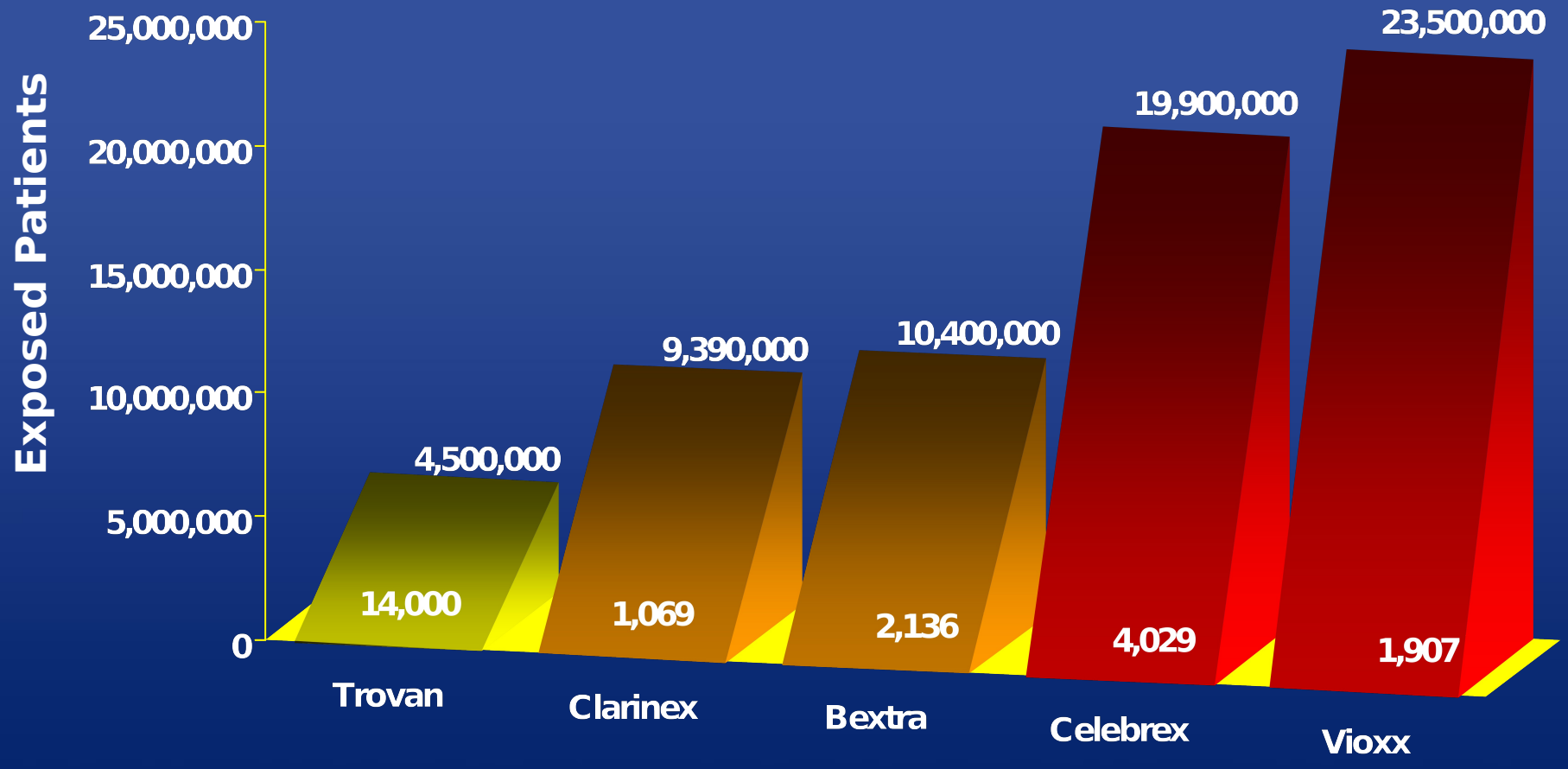
Pivotal Studies vs. Market Size



IMS Market Share, 2003; Express Scripts literature review, 2005

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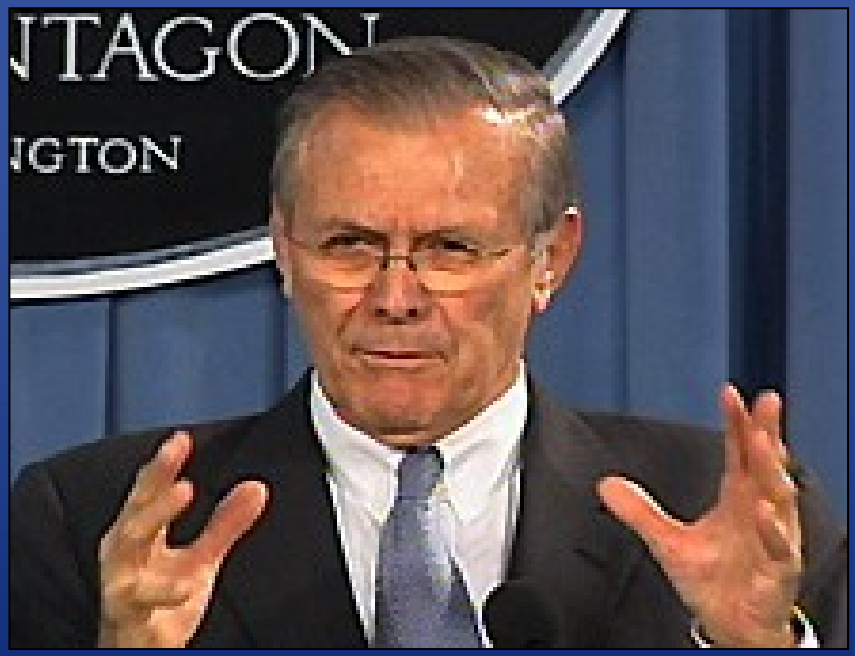
“…There are things we don’t know we don’t know.”



Donald Rumsfeld
Secretary of Defense
United States of America
May 22, 2002

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Rumsfeld's Rule: "We Don't Know We Don't Know..."

	Knowns (Established Risks)	Unknowns (Undiscovered Risks)
Known		
Unknown		

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Rumsfeld's Rule: "We Don't Know We Don't Know..."

	Knowns (Established Risks)	**Unknowns** (Undiscovered Risks)
Known	Prompted or remembered	
Unknown	Forgotten or never learned	

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Rumsfeld's Rule: "We Don't Know We Don't Know..."

	Knowns (Established Risks)	**Unknowns** (Undiscovered Risks)
Known	Prompted or remembered	
Unknown	Forgotten or never learned	Always a surprise

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Rumsfeld's Rule: "We Don't Know We Don't Know..."

	Knowns (Established Risks)	**Unknowns** (Undiscovered Risks)
Known	Prompted or remembered	Cautious Prescribing
Unknown	Forgotten or never learned	Always a surprise

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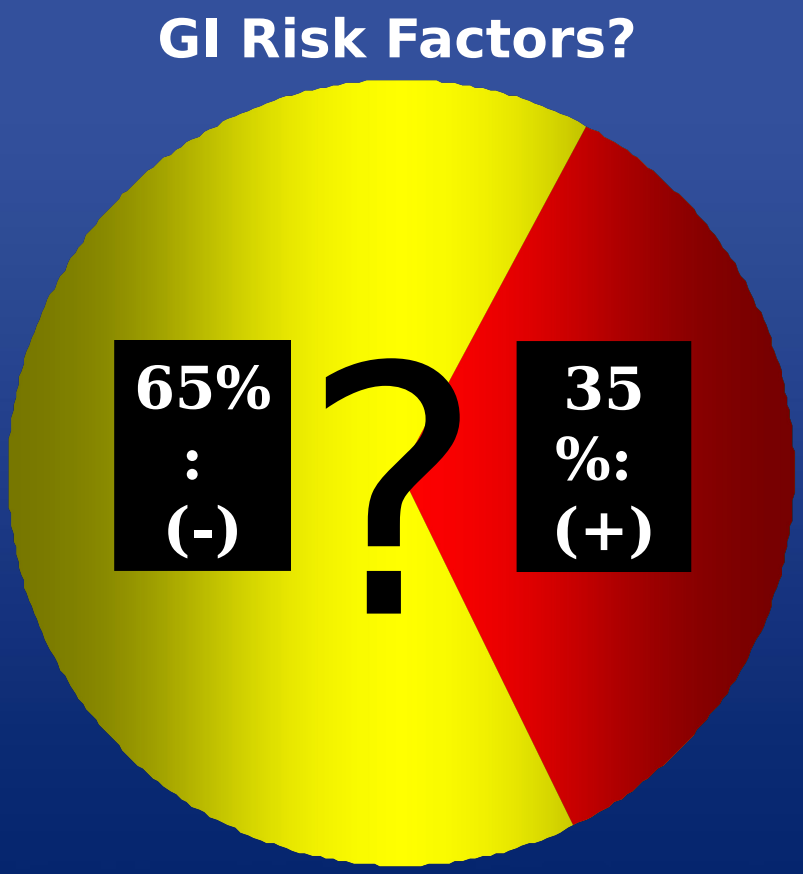
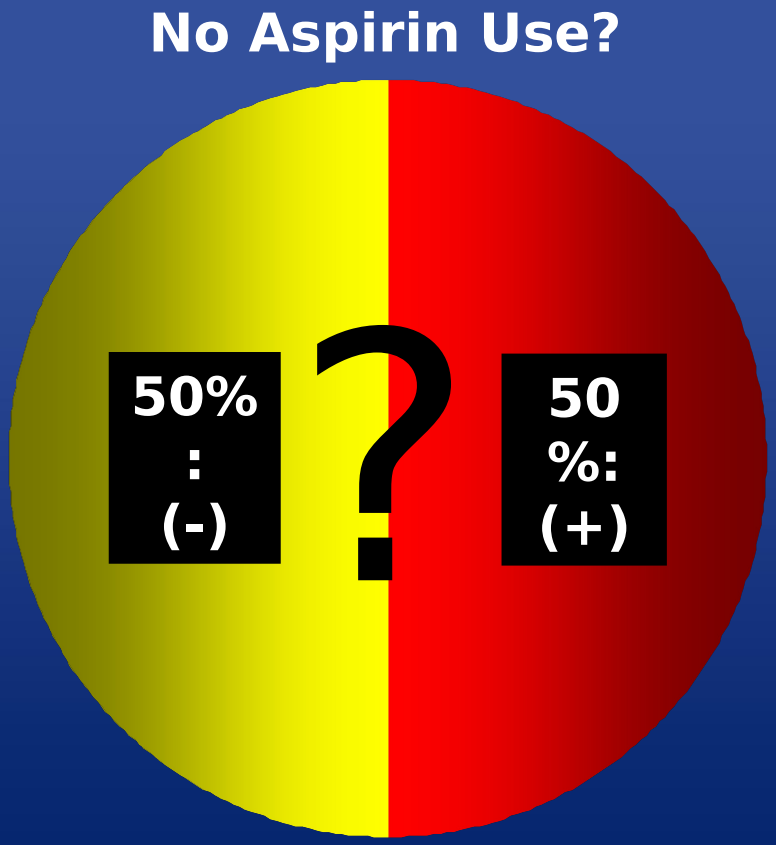
How Cautious Were COX-2 Prescribers?





Cox ER. *American Journal of Managed Care*. 2003;9(11):735-742.

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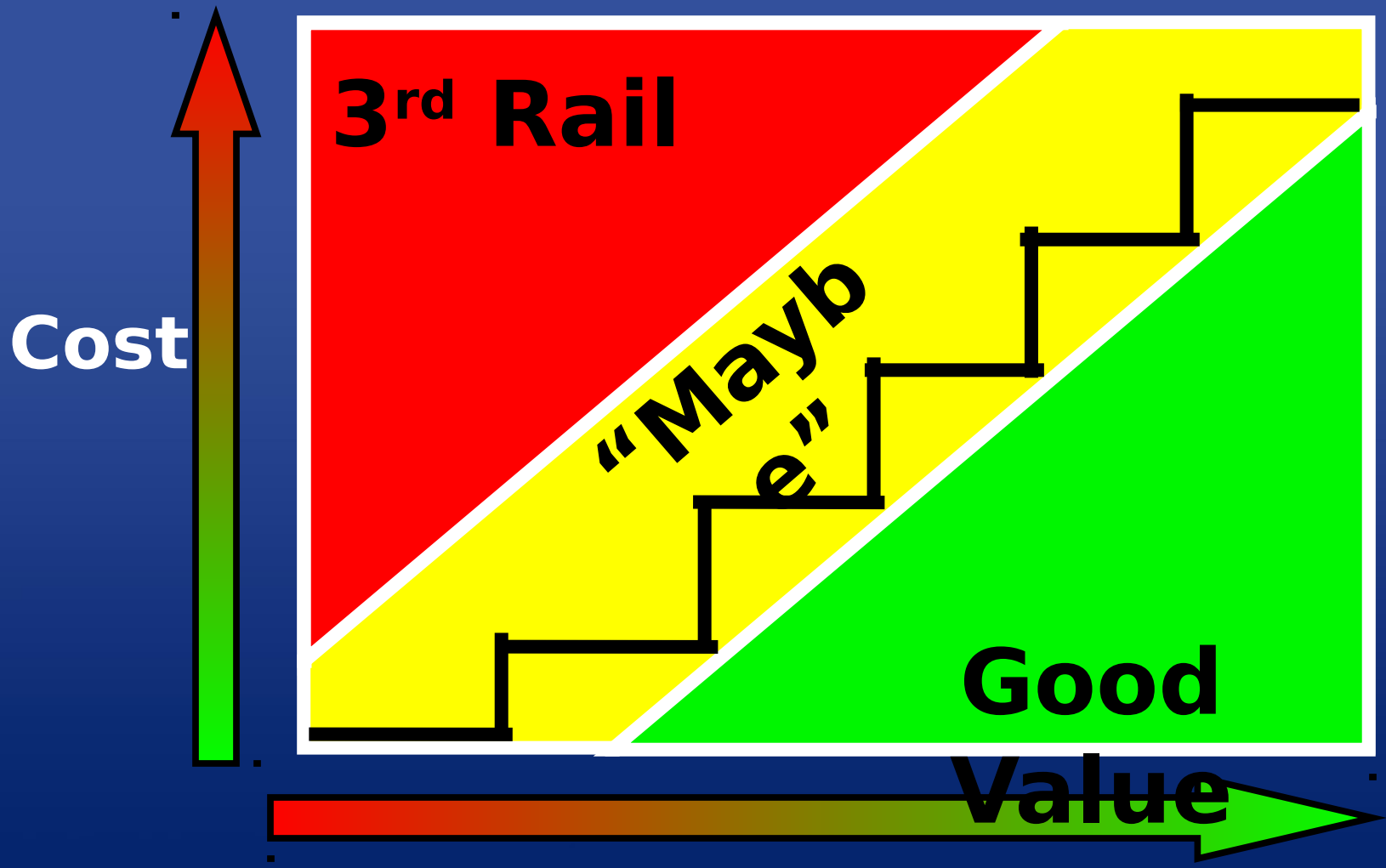
Stepping Through the "Maybe" Zone



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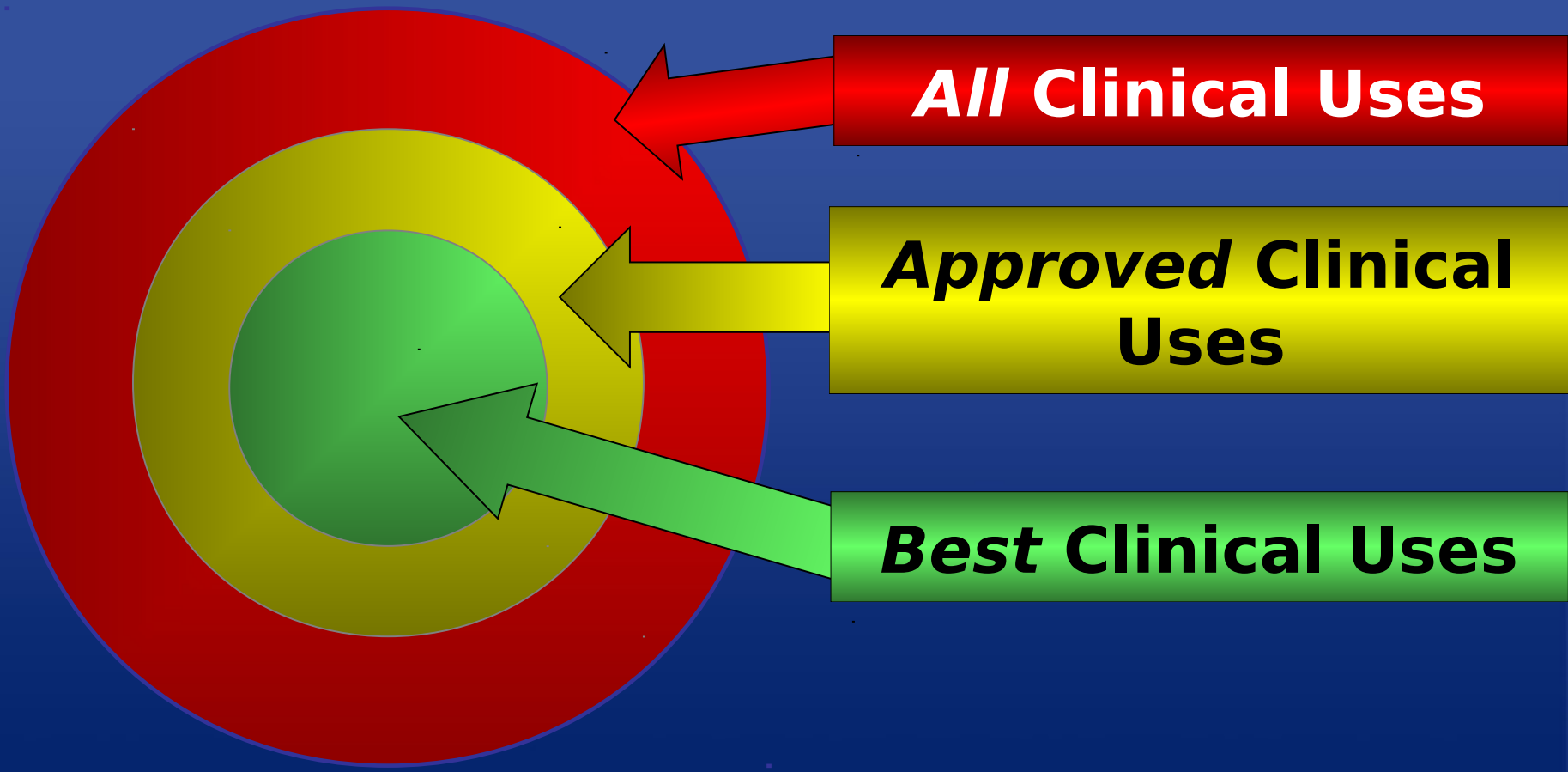
Formularies, Step Therapy, PA: Not Just Trend Management



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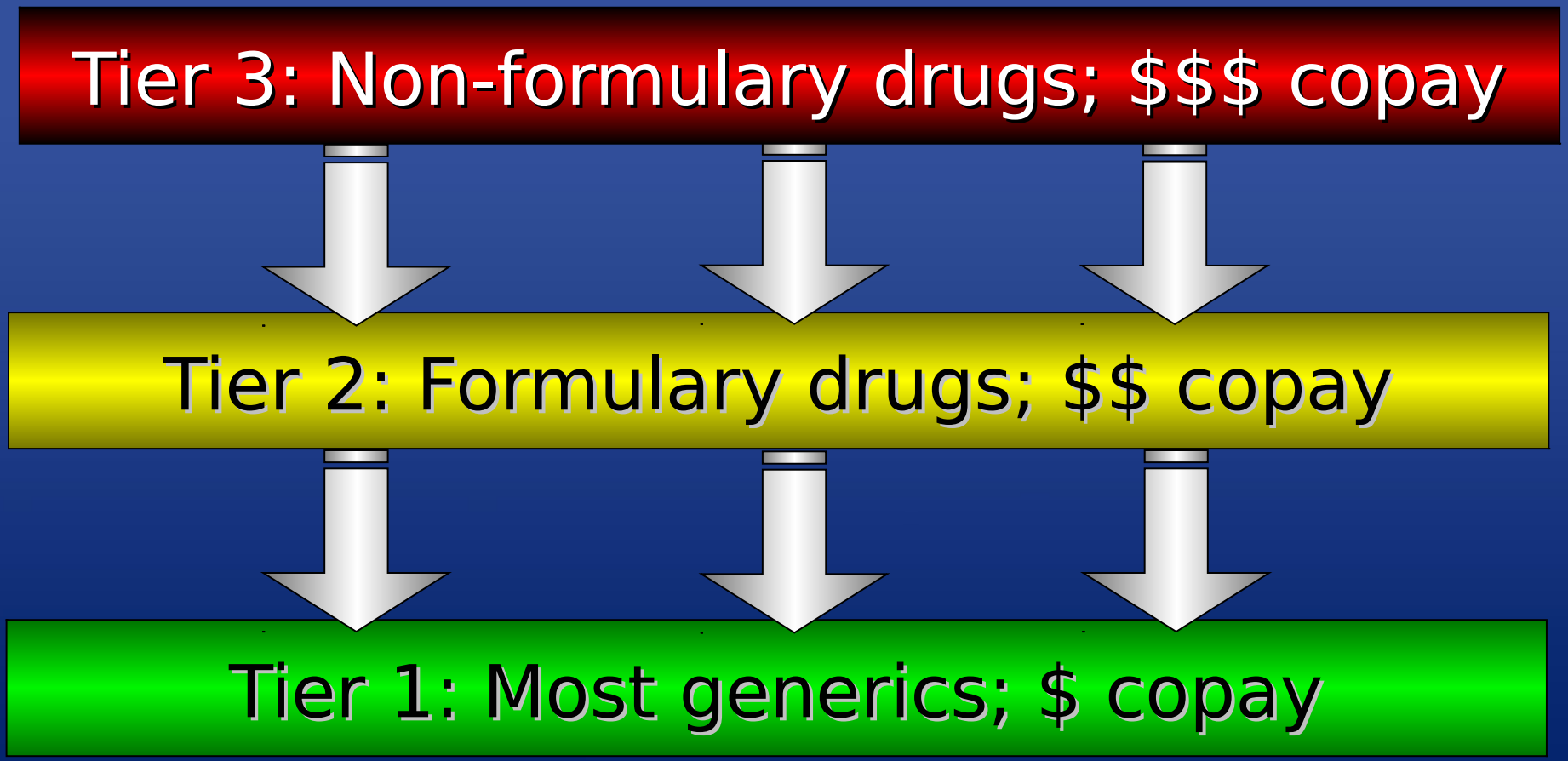
Leveraged Prescribing: Formulary Design



Express Scripts *Drug Trend Report 2003*

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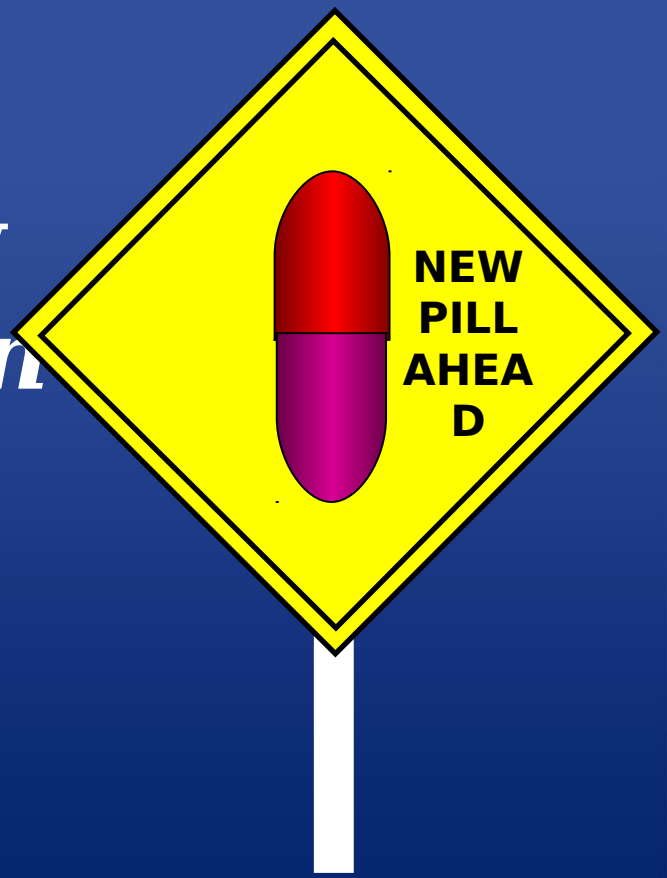
Take Unknown Risks *Wisely*

Focus the use of new drugs on their *proven* clinical advantages.



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Improving Safety: Step Three

Manage The Risk

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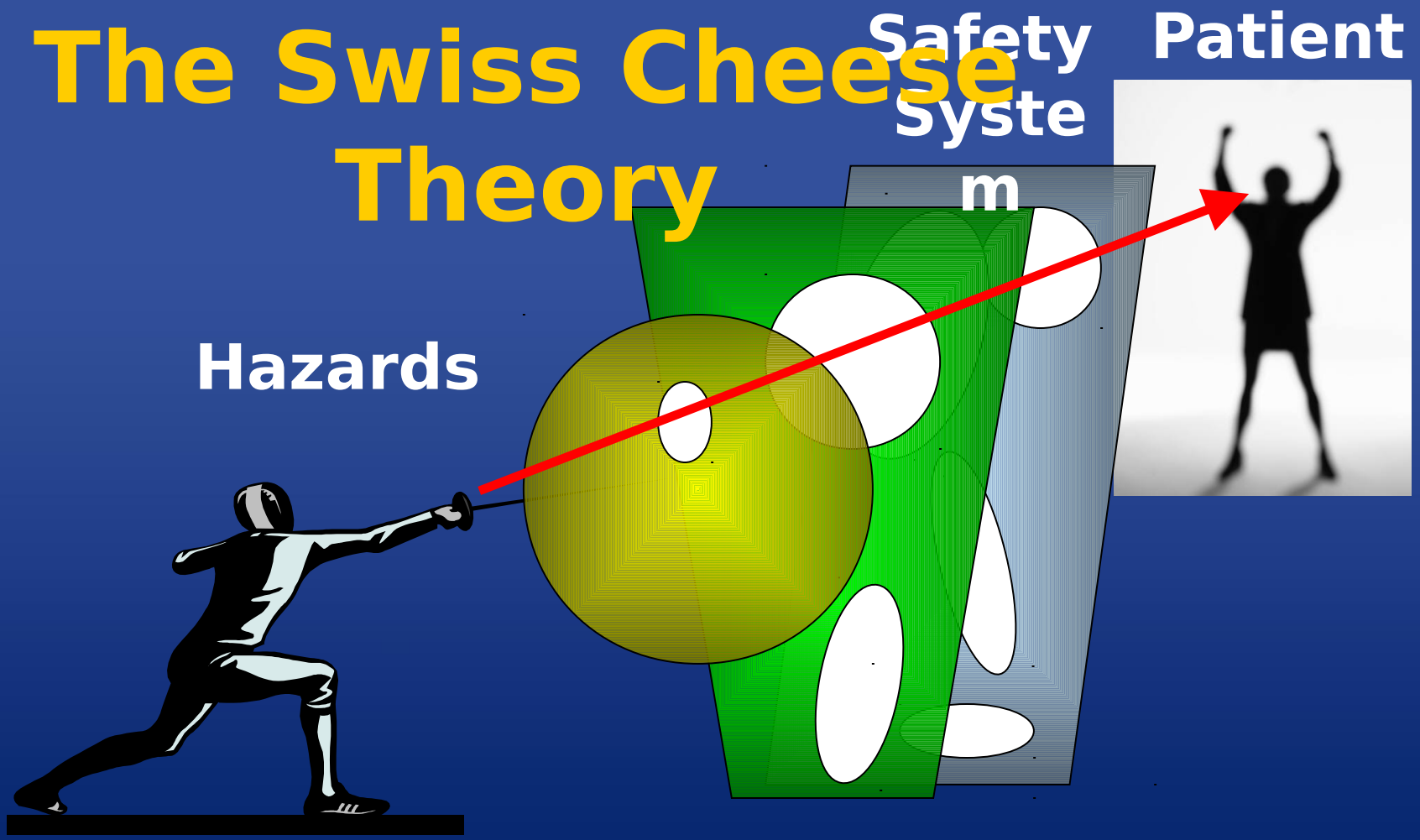
The Swiss Cheese Theory



Reason, J. *Managing the Risks of Organizational Accidents.* Brookfield, VT: Ashgate. 1997

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4 Systems For Safer Prescribing

1. Drug Utilization Review
2. Emerging Information Management
3. Rx Distribution Network
4. Electronic Prescribing

Plus many more…

- Pharmacogenomics / Personalized Medications
- Medicare Part D
- Patient Safety Organizations

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Current Safety Tool #1:

Drug Use Review ("DUR")

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Drug Use Review – Two Flavors

Concurrent

- Real-time
- Disruptive
- Best for severe or rapid-onset ADE

Retrospective

- Letters
- After adjudication
- Monitoring
- *Patterns* of care

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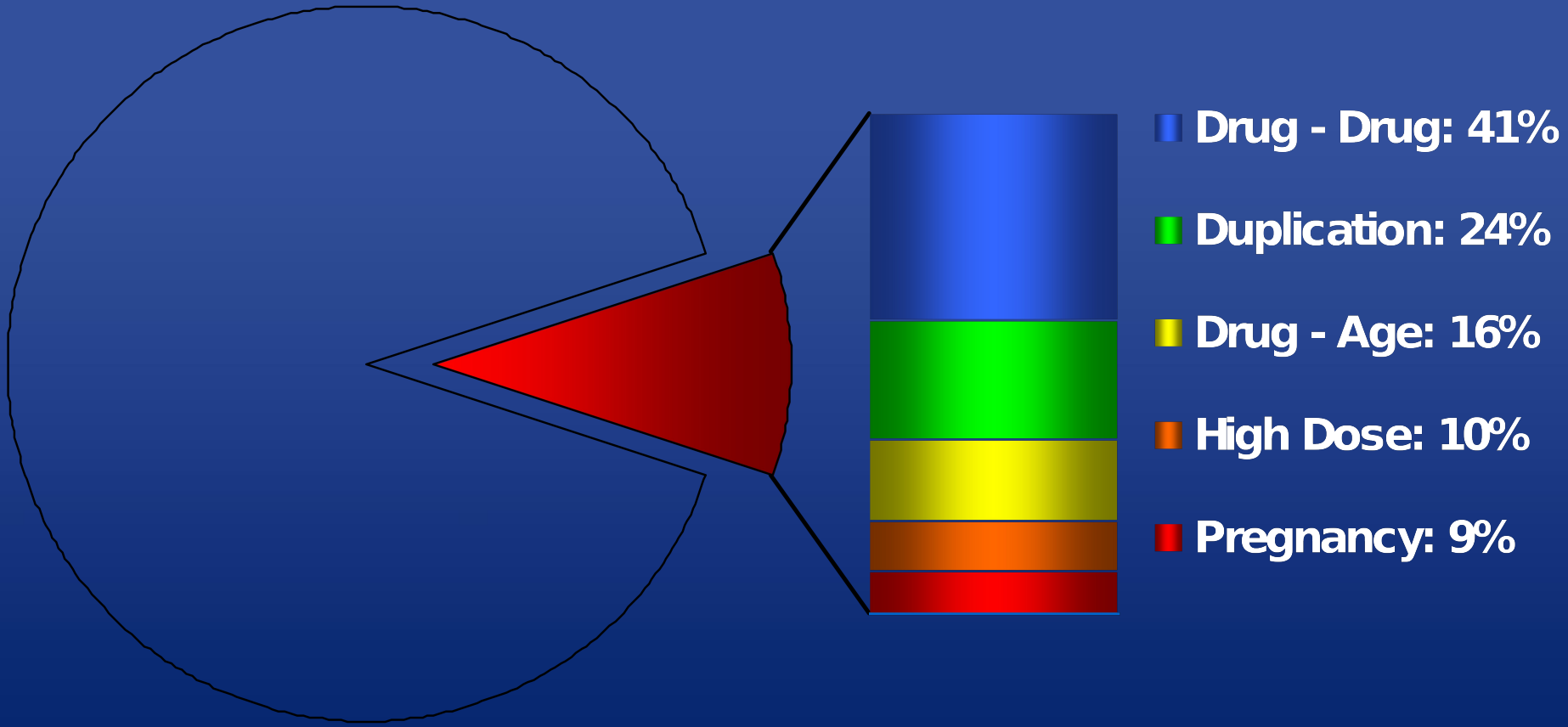
cDUR: 10.3% of All Prescriptions



- Overall number from Chui and Rupp. *JMCP* 2001
- Category percentages based upon complete ESI data Oct and Nov 2003

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88% of DDI alerts are over-ridden

34%: “Already Knew About It”

34% “Don’t Believe It’s Real”

27%: “It’s Not Important”

5%: other

Which ones are actually important?

Chui and Rupp. *JMCP* 2001

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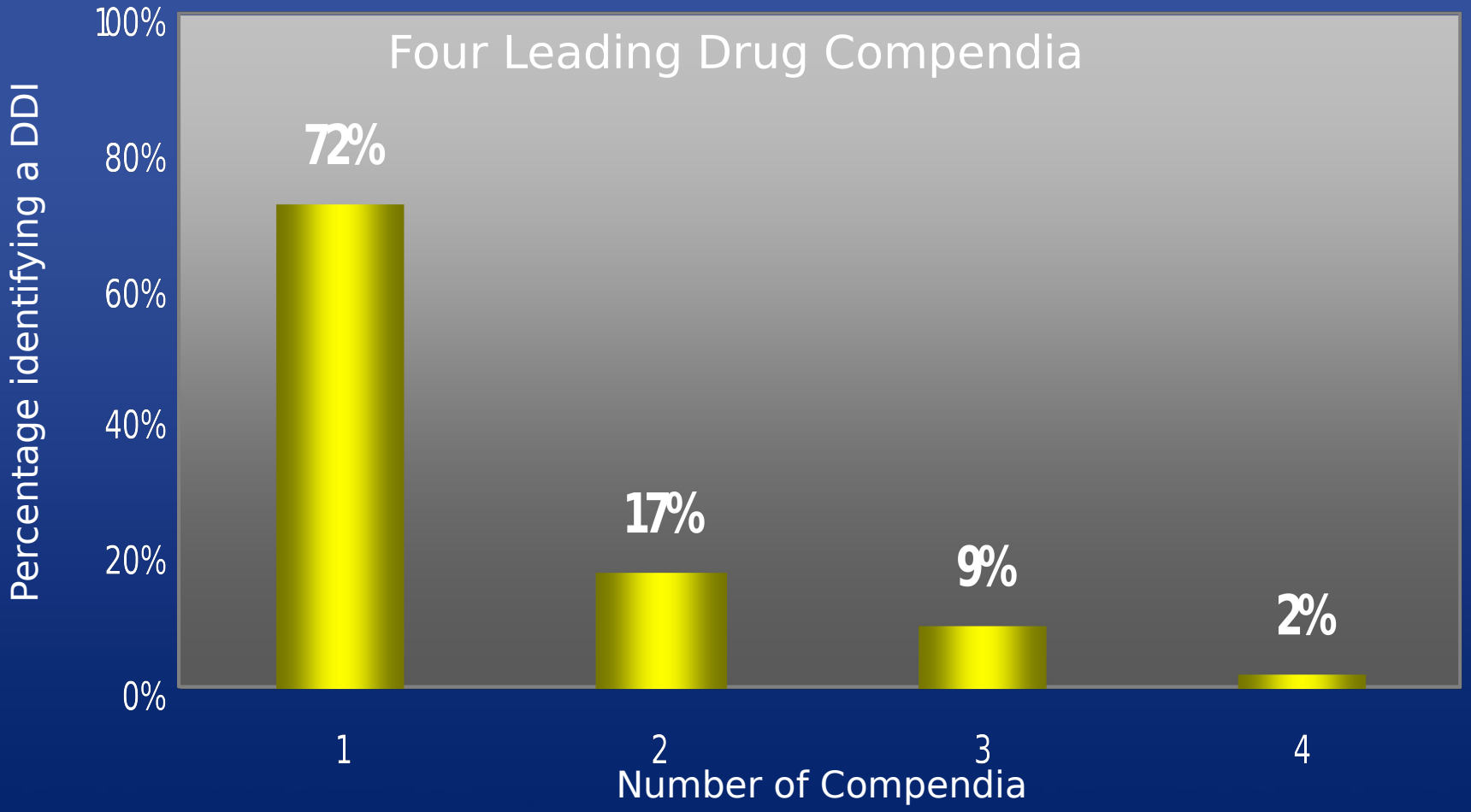
Concordance of DDI Information



Abarca, J. et al. *J Am Pharm Assoc*. 2004; 44:136-141

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ESI DUR Enhancement Project

Examples of Alerts We Do Not Send to Pharmacies:

- Standard of care
  - *e.g.*, methotrexate and NSAIDs
- Overly generalized inpatient alerts
  - *e.g.*, cimetidine and lidocaine
- Some were just plain silly
  - *e.g.*, pregnancy and oral contraceptives
- Many other categories

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ESI DUR Enhancement Project

- **Enhanced targeting by 33%**
  - Reduced false-positive signals
  - Logical inclusion algorithm
  - Validated with historic impact of specific edits
- **Require intervention/outcome codes**
- **Studying impact in 2006**

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Drug Use Review

Retrospective

- Letters
- After adjudication
- Monitoring
- *Patterns* of care

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What's In Our Retro-DUR?

Clinical Target	Example
Drug-Disease	Asthma on beta-blockers
Duplicate Therapies	Two simultaneous ACE Inhibitors
Suboptimal therapy	Triptans without prophylaxis
Under-utilization	Asthma without controllers
Senior Drugs of Concern	Amitriptyline
Many more modules…	Over-Utiliz., Preg., Addictives…

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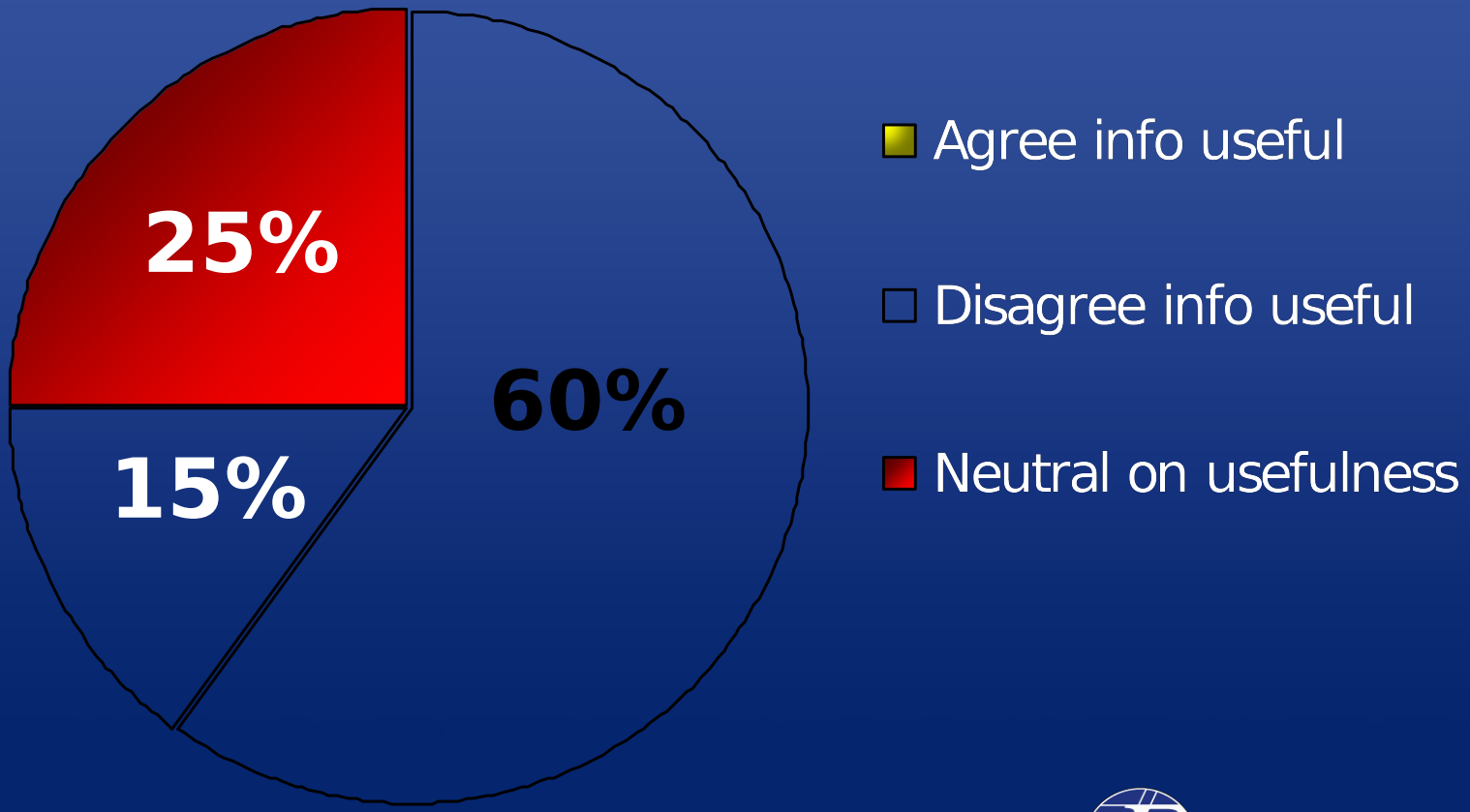
Prescribers Appreciate rDUR

…but does it work?



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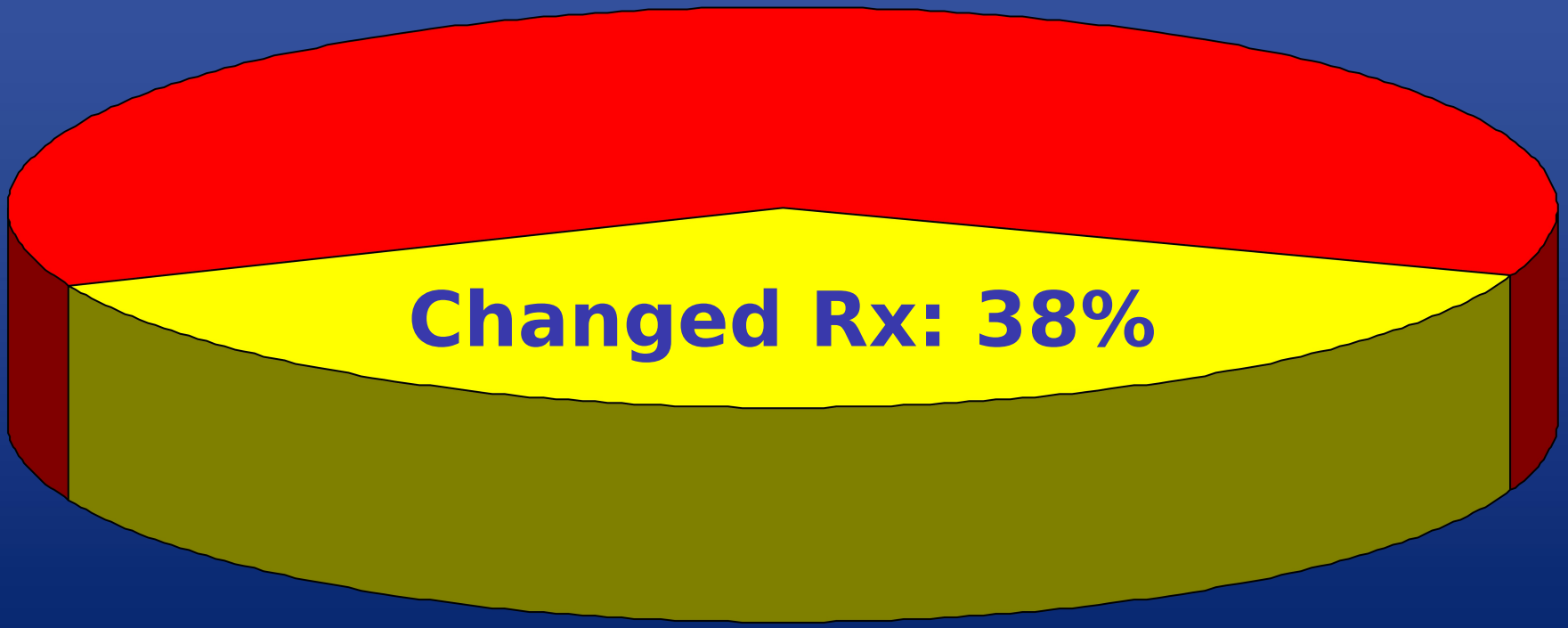
ESI Physician Survey:

Retro-DUR Changes Treatment Plans



Express Scripts Prescriber Survey, 2003

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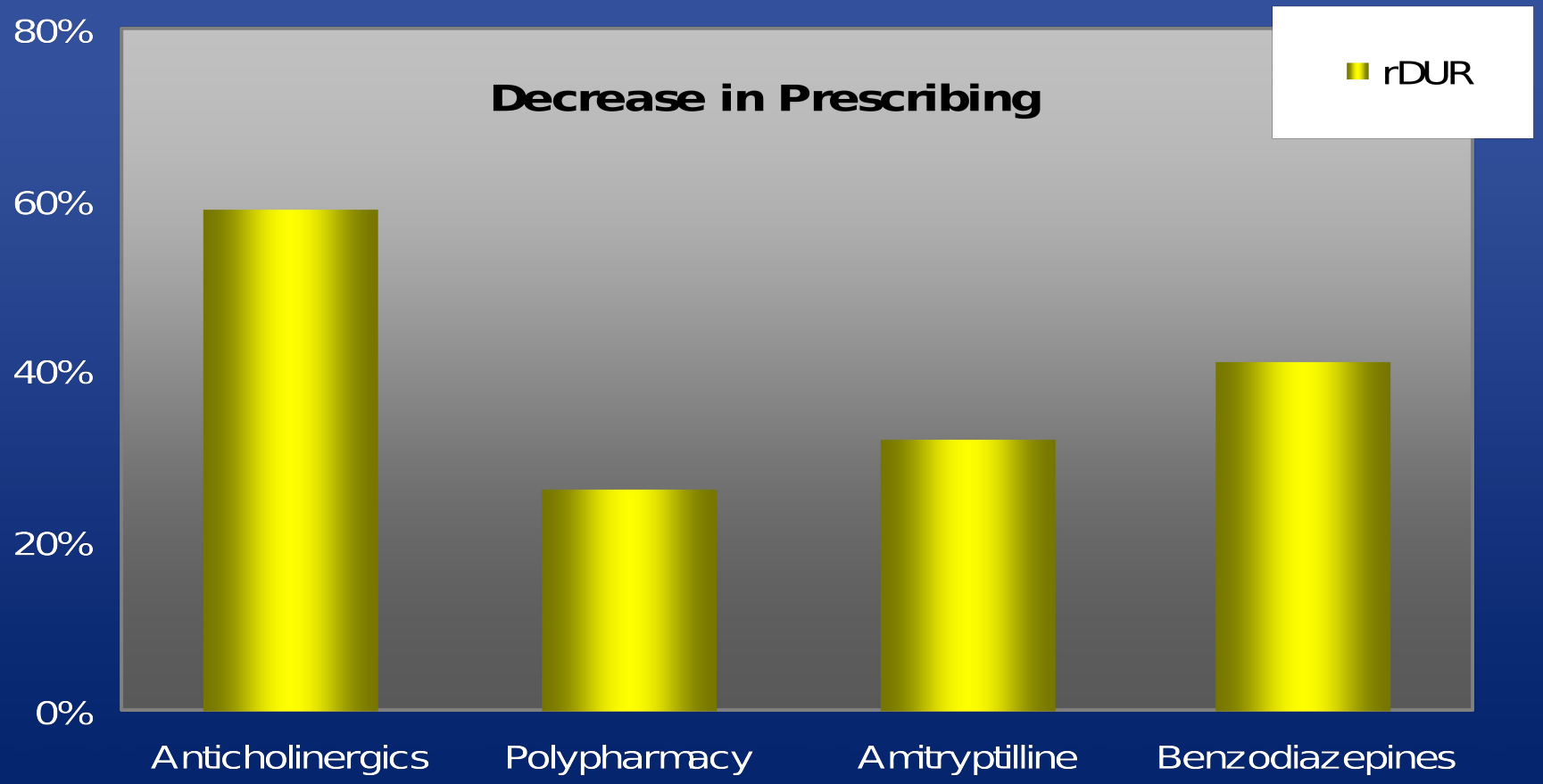
Retro-DUR: Express Scripts RCT

Six months pre- and post- rDUR message to prescriber



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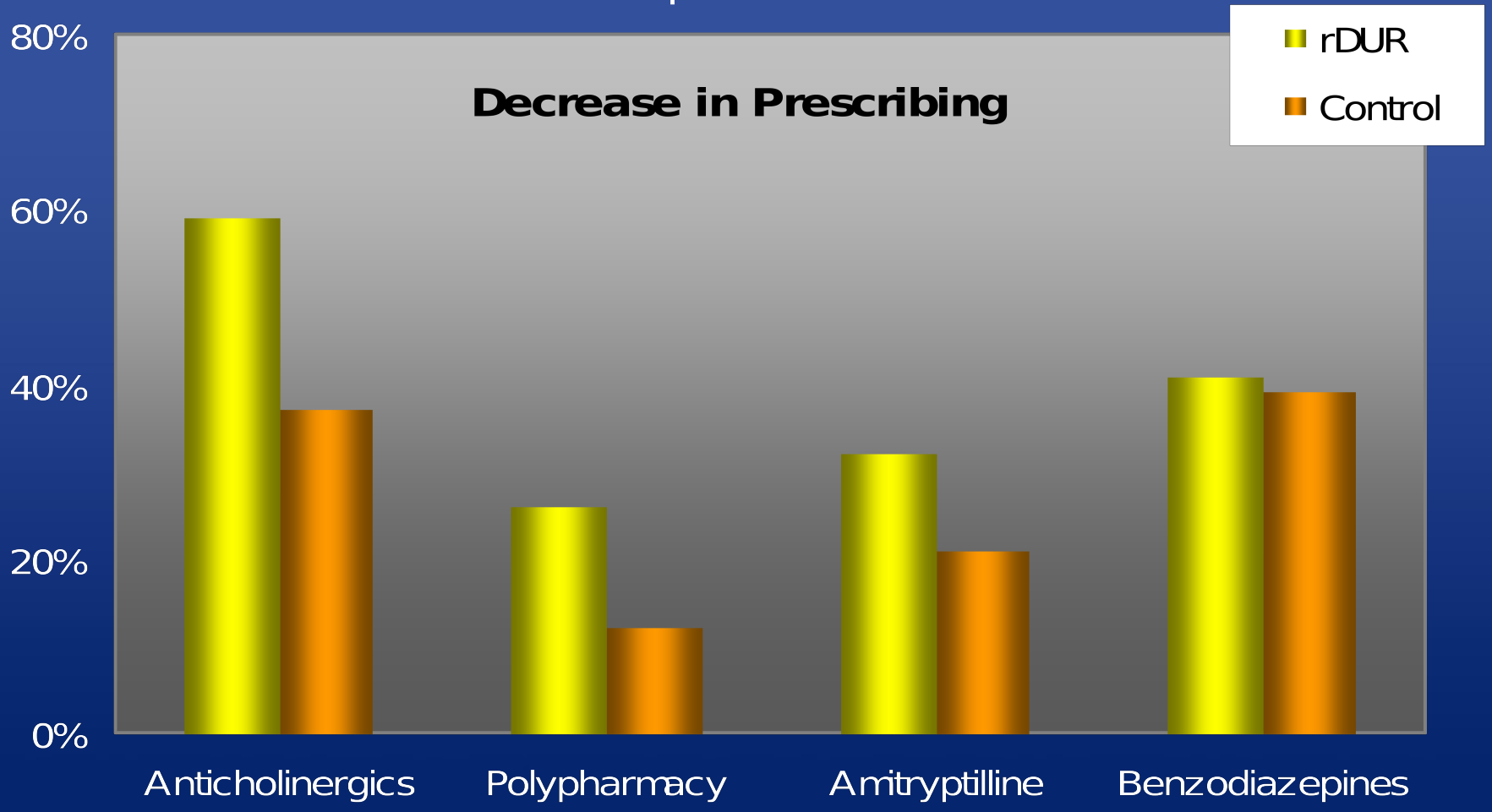
Retro-DUR: Express Scripts RCT

Six months pre- and post- rDUR message to prescriber



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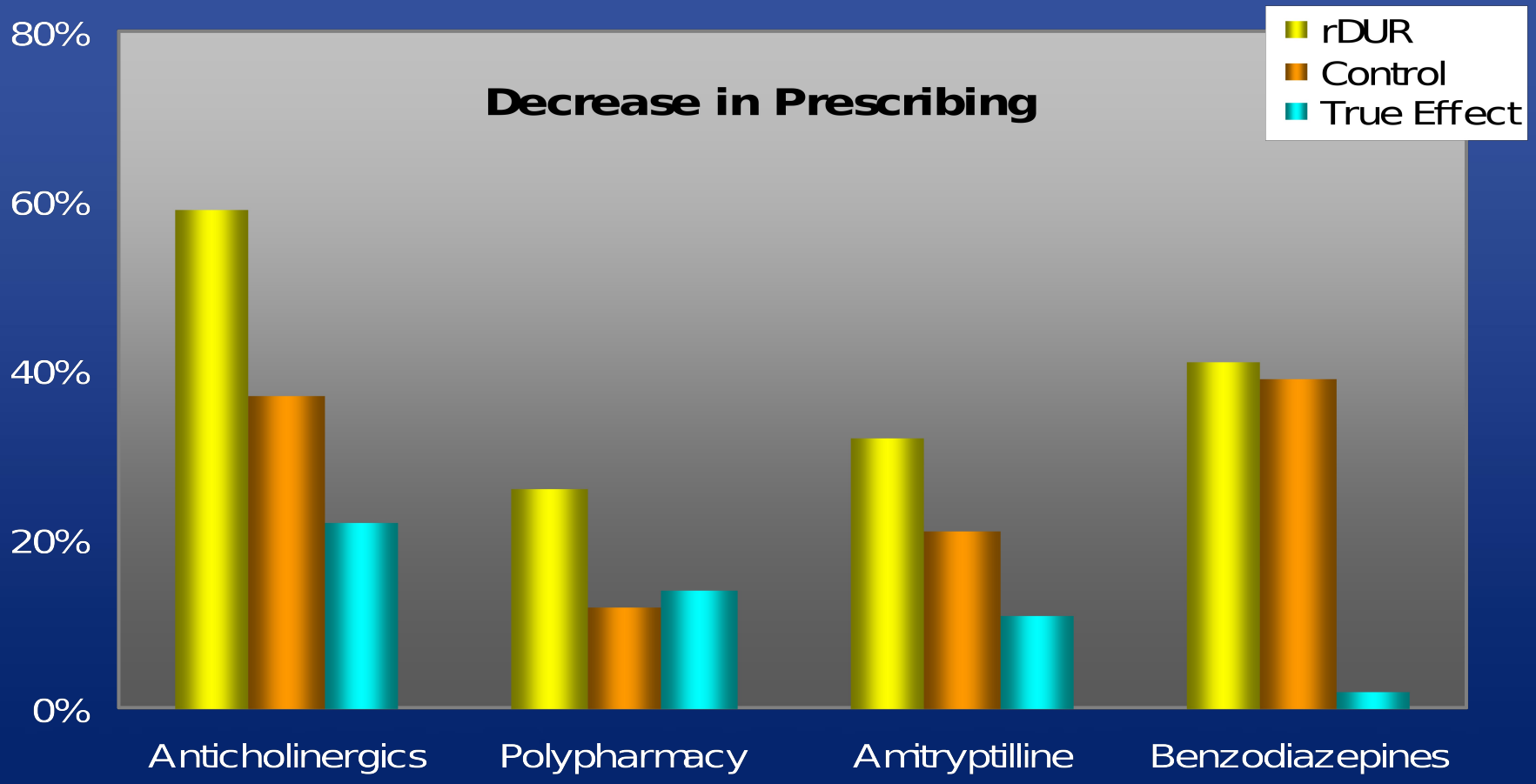
Retro-DUR: Express Scripts RCT

Six months pre- and post- rDUR message to prescriber



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Retrospective DUR

Would you want a car without one of these?

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Current Safety Tool #2:

Emerging Therapeutic Information Management

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33 Interventions in the Past 5 Years

- **Typical drivers**
  - FDA Advisories
  - Drug Recalls
  - Drug Lot Recalls
- **Letters to patients, health plans and/or prescribers**
- **Prescriber letters may include list of affected patients**

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Selected ETI Interventions

Date	Issue	Prescriber Letters	Patient Letters	Client Letters
June ’05	Palladone withdrawal	Yes	Yes	Yes
April ’05	Paxil seizure by FDA	No	No	Yes
April ’05	Bextra withdrawal	Yes	Yes	Yes
Feb. ’05	Neurontin lot recall	No	Yes	Yes
Oct. ‘04	Antidepressant warning in children	Yes	No	Yes

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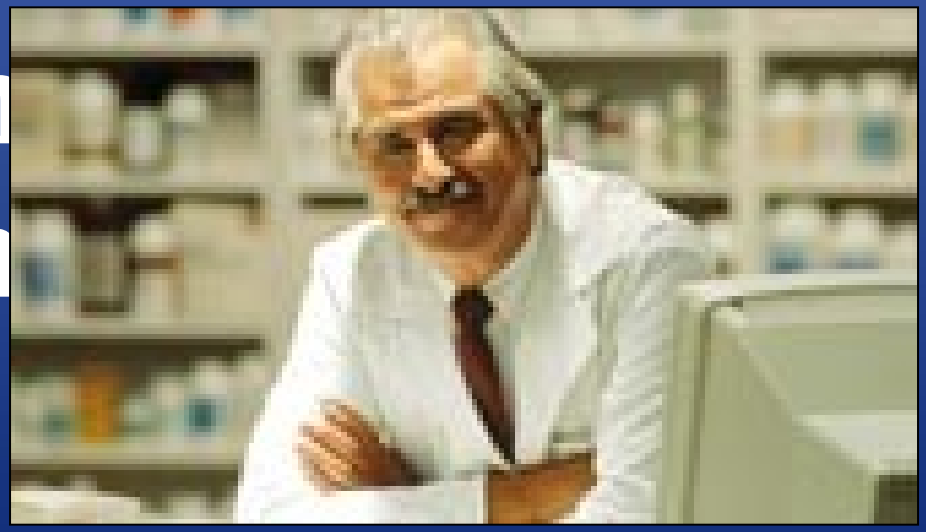
Safety System #3:

Prescription Distribution Network



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Distribution Network *Matters*

	Retail Pharmacies	Mail Order
Regulated		
Staffing		
Automation		
Drug history		
Counselling		
DUR		
Workload		

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Distribution Network *Matters*

	Retail Pharmacies	Mail Order
Regulated	State boards	State boards
Staffing	RPh and Techs	RPh and Techs
Automation		
Drug history		
Counselling		
DUR		
Workload		

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Distribution Network *Matters*

	Retail Pharmacies	Mail Order
Regulated	State boards	State boards
Staffing	RPh and Techs	RPh and Techs
Automation	Limited	**Comprehensive**
Drug history	Local	**Comprehensive**
Counselling	At counter (when open)	**Private (24x7)**
DUR	Variable	**Consistent**
Workload		

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How Consistent Is Retail cDUR?

Let's look…

- 6 sham patients
- 16 *well-documented* DDIs
- 516 community pharmacie

Hazlet TK. *J. Am Pharm Assn*. 2001; 41:200-204

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Wide Variation In cDUR Performance

Retail missed 35% of these interactions.

Express Scripts finds 100% of them.

Which do you prefer?

Hazlet TK. *J. Am Pharm Assn*. 2001; 41:200-204

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Distribution Network *Matters*

	Retail Pharmacies	Mail Order
Regulated	State boards	State boards
Staffing	RPh and Techs	RPh and Techs
Automation	Limited	**Comprehensive**
Drug history	Local	**Comprehensive**
Counselling	At counter (when open)	**Private (24x7)**
DUR	Variable	**Consistent**
Workload		

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Distribution Network *Matters*

	Retail Pharmacies	Mail Order
Regulated	State boards	State boards
Staffing	RPh and Techs	RPh and Techs
Automation	Limited	**Comprehensive**
Drug history	Local	**Comprehensive**
Counselling	At counter (when open)	**Private (24x7)**
DUR	Variable	**Consistent**
Workload	**Beginning of the month**	**Consistent**

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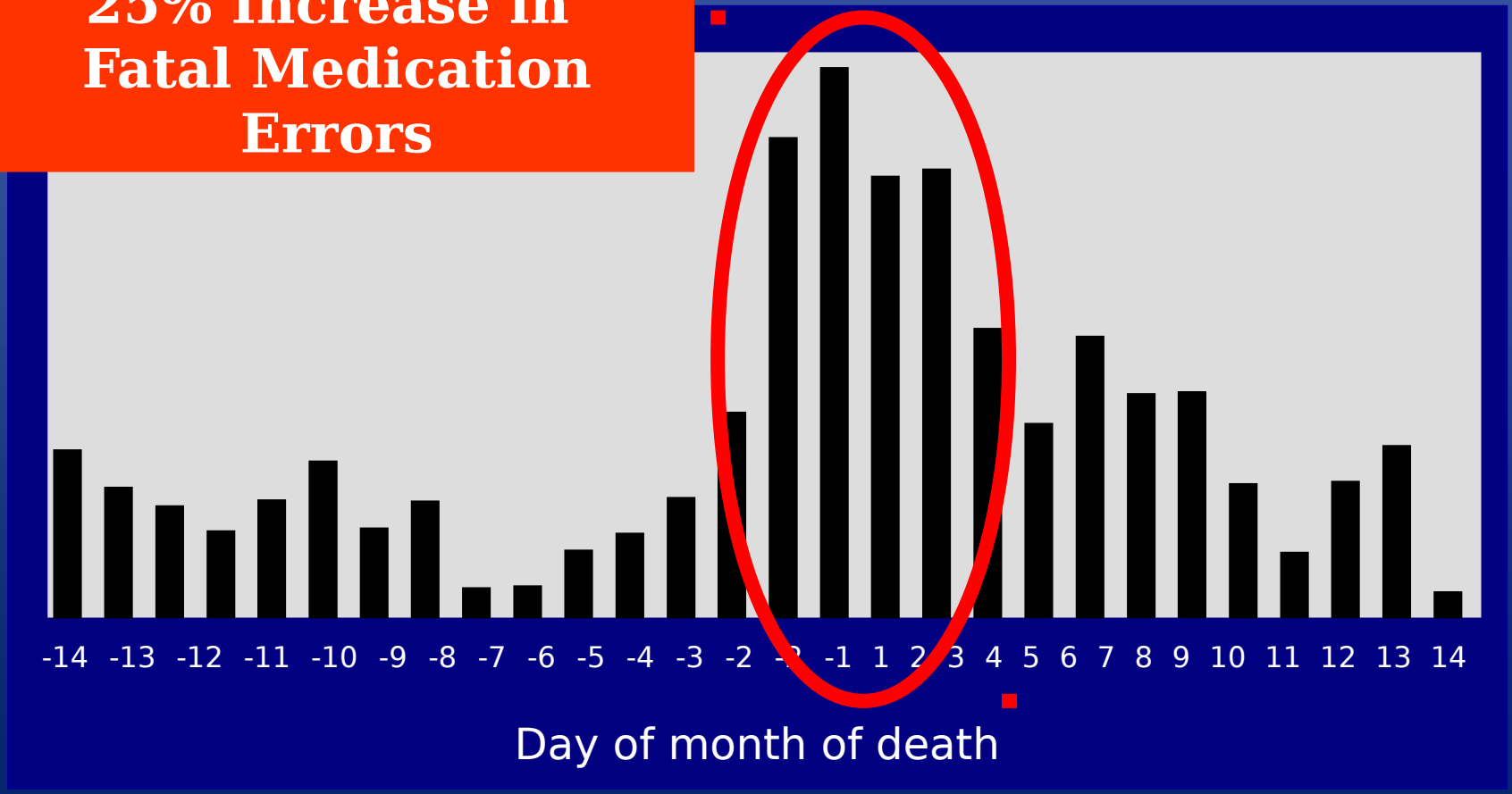
Beginning of the Month Effect (The "BOME")

25% Increase in Fatal Medication Errors



Phillips, D. A Spike in Fatal Medication Errors at the Beginning of Each Month. *Pharmacotherapy* 2005;25(1):1-9.

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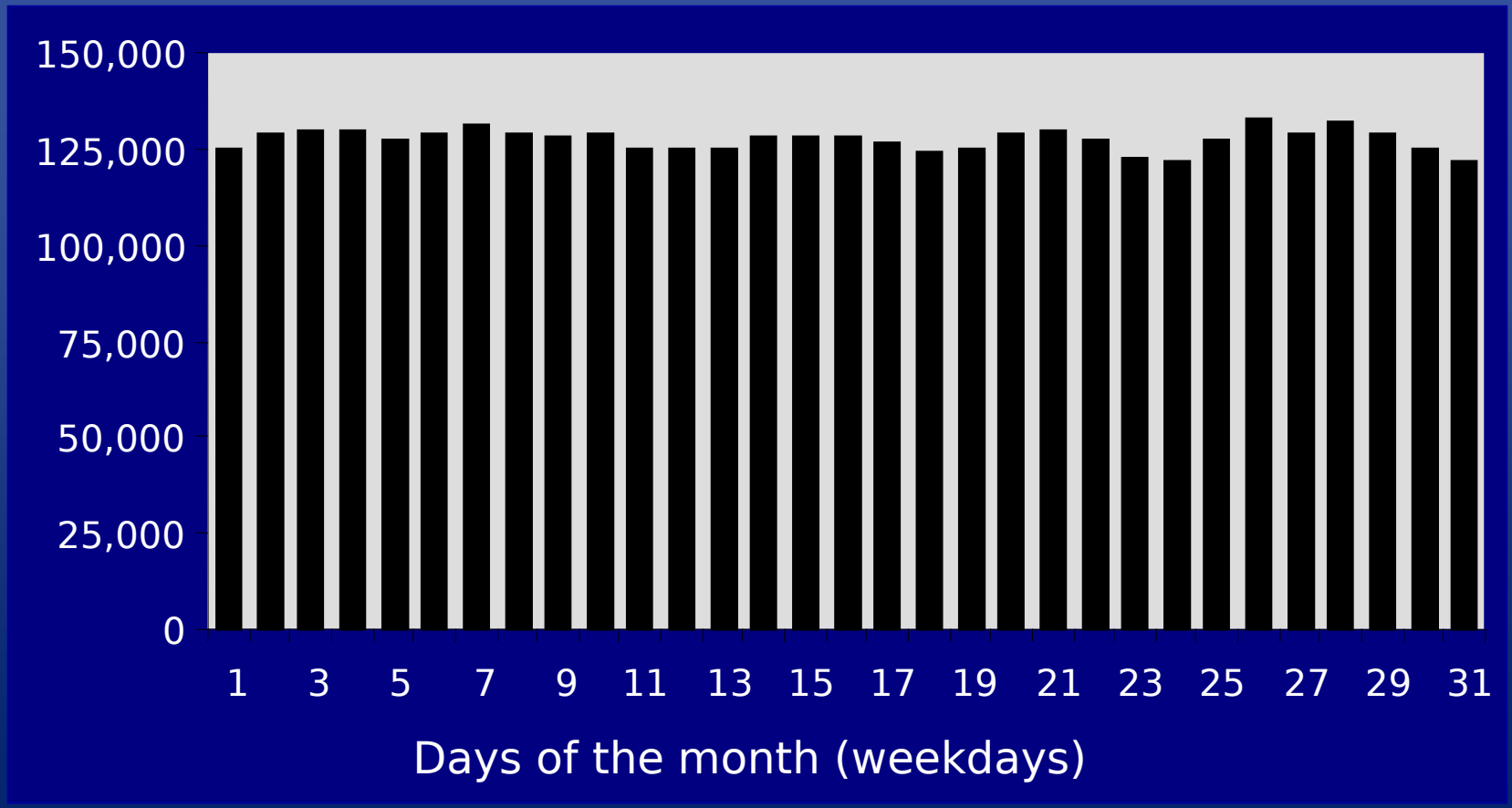
No “BOME” In Volume At Mail



Express Scripts mail, 4 month average, 01/05 through 04/05

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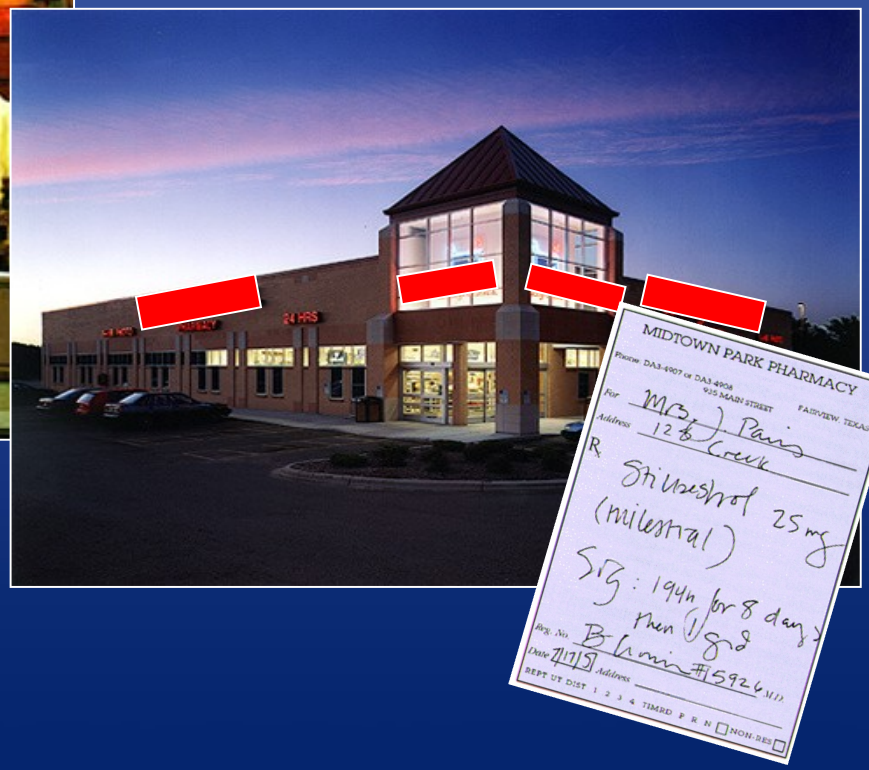
Let's Order Carry-Out Tonight…

Order:

Hot and Sour Soup

(2) (To go)



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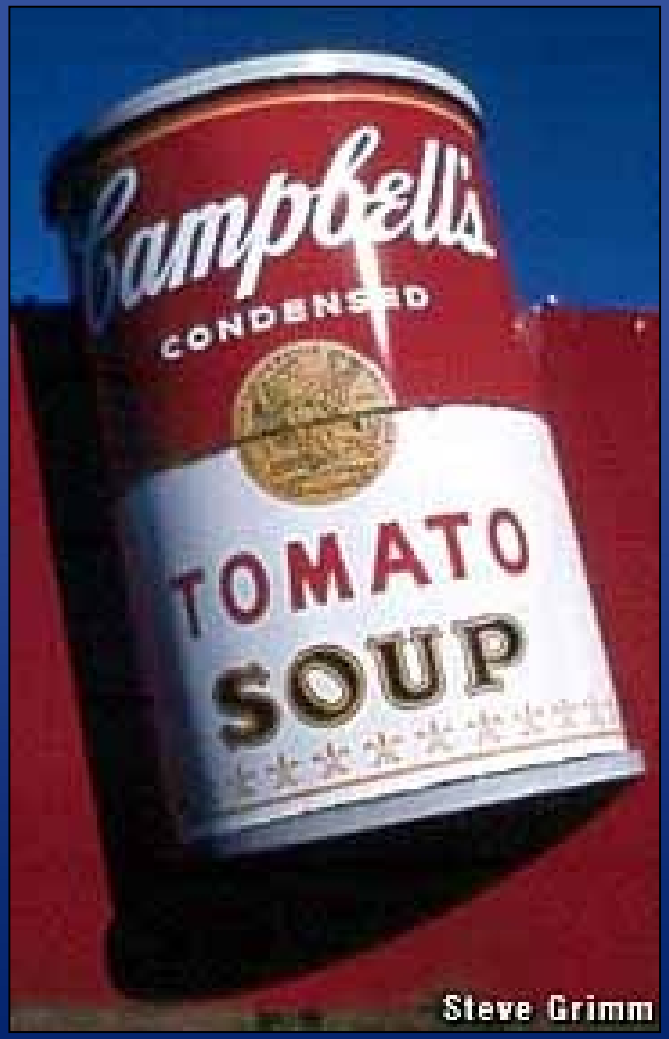
You know it's got tomato soup inside.



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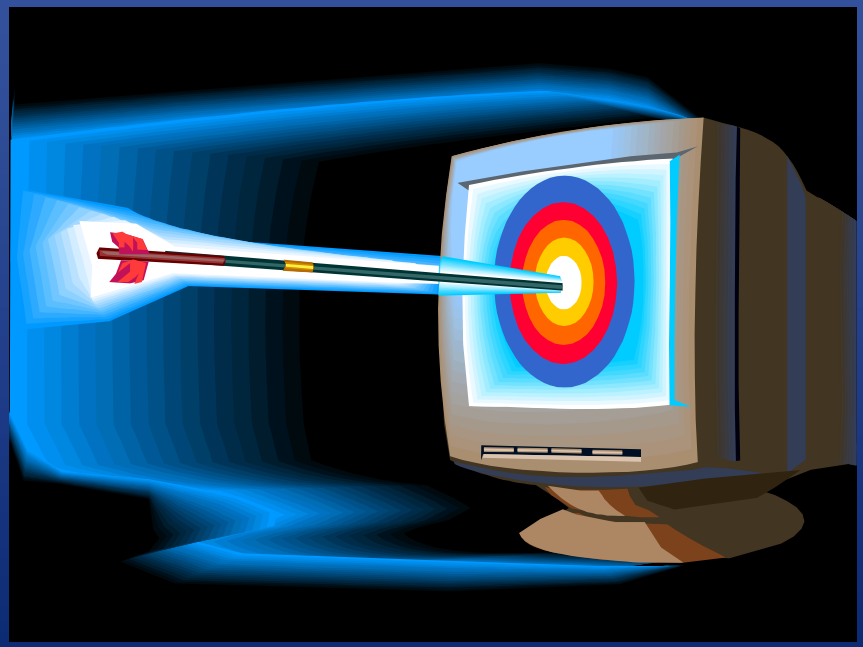
Safety System #4:

Electronic Prescribing



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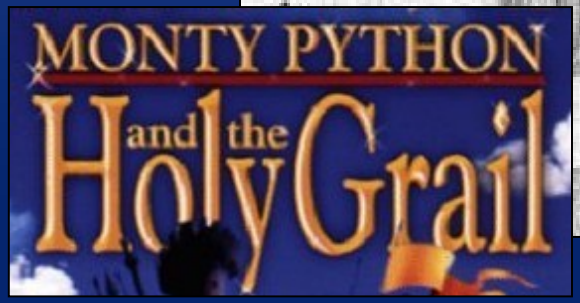
Start With A Strong IS Team



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“Paper kills.”

Newt Gingrich, speaking at AMCP, April 21, 2005

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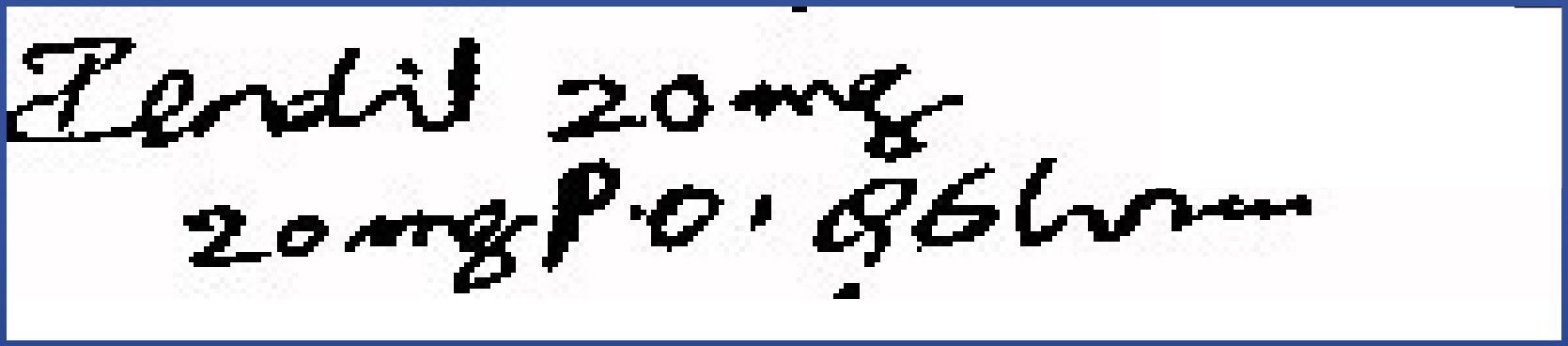
Name That Drug…



- **Intended Rx:** Isordil (for angina)
- **Filled Rx:** Plendil (for blood pressure)
- *Patient suffered a fatal heart attack a few days later*

Institute for Safe Medicine Practices, *Safe Medicine Alert*, July 16, 1997

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It’s Not Just About Handwriting

- No difference between computerized and manual Rx systems.
- **Advanced systems** could have prevented 35% of the events.

Gandhi, TK. *NEJM* 2003; 348:1556-64

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Basic E-Rx

- Rx printed and given to patient
- Passive references

Intermediate E-Rx

- Rx electronically transmitted to pharmacy
- Decision support (interactions, allergies, cost)

Advanced E-Rx

- Sophisticated data streams (EDI, ICD-9, CPT, etc.)
- Proactive drug recommendations
- Preventive monitoring

Center for Information Technology Leadership. *The Value of Computerized Provider Order Entry in Ambulatory Settings.* 2003

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Projected US Annual Avoided Events

81% adoption…	Basic	Intermediate	Advanced
Ambulatory Visits	136,000	783,000	1,293,000
Total ADEs	218,000	1,2252,000	2,068,000
Life-threatening ADES	14,300	82,620	136,100
Hospitalizations	20,800	115,400	191,100

Center for Information Technology Leadership. *The Value of Computerized Provider Order Entry in Ambulatory Settings.* 2003

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Why Not 100% E-Rx Today?

- Workflow
- Capital
- Vendors
- Interoperability
- Regulatory
- Healthcare's Dirty Little Secrets…

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Healthcare's 3 Dirty Little Secrets

- "Paper may kill, but obfuscation pays."
- "Bad quality is good for business."
- "One organization's unnecessary product is other's revenue stream."

Kleinke, J. *Health Affairs.* Sept/Oct 2005. 24: 1246.

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Still, Adoption Is Growing

- Standards emerging
- Safe Harbors emerging
- VA EMR available
- Incentives increasingly aligned (P4P)
- MMA will eventually require E-Rx
  - Influx of capital inevitable

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62% of hospitals plan to have Electronic Medical Records within 2 years.

Healthcare Information Management and Systems Society, Annual Conference, February 2005, Dallas TX

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One doctor in four plans to buy an EHR soon

% who plan to buy an EHR in the next 12 months					
By specialty		**By age**		**By practice size**	
FPs/GPs	27%	Under 35	27%	Solo	18%
Internists	24	35-44	28	2 doctors	24
Ob/gyns	19	45-54	26	3-10 doctors	23
Pediatricians	23	55-64	20	11-20 doctors	37
All respondents	23	65+	10	21+ doctors	36

Terry, K. *Medical Economics* January 21, 2005. 82:2:72-84

"Seeing your physician use pen and paper
is probably more dangerous to your health
than [illegible] ke."

Paul Wallace, MD, January 12, 2005 speaking at SOS Rx

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5 Key Lessons for Practicing Physicians

1. ADEs are happening today. ***Your*** patients have them.
2. Less is more.
3. Computers are not typewriters.
4. Generic drugs, tried and true.
5. You wanted pepperoni? Sorry.

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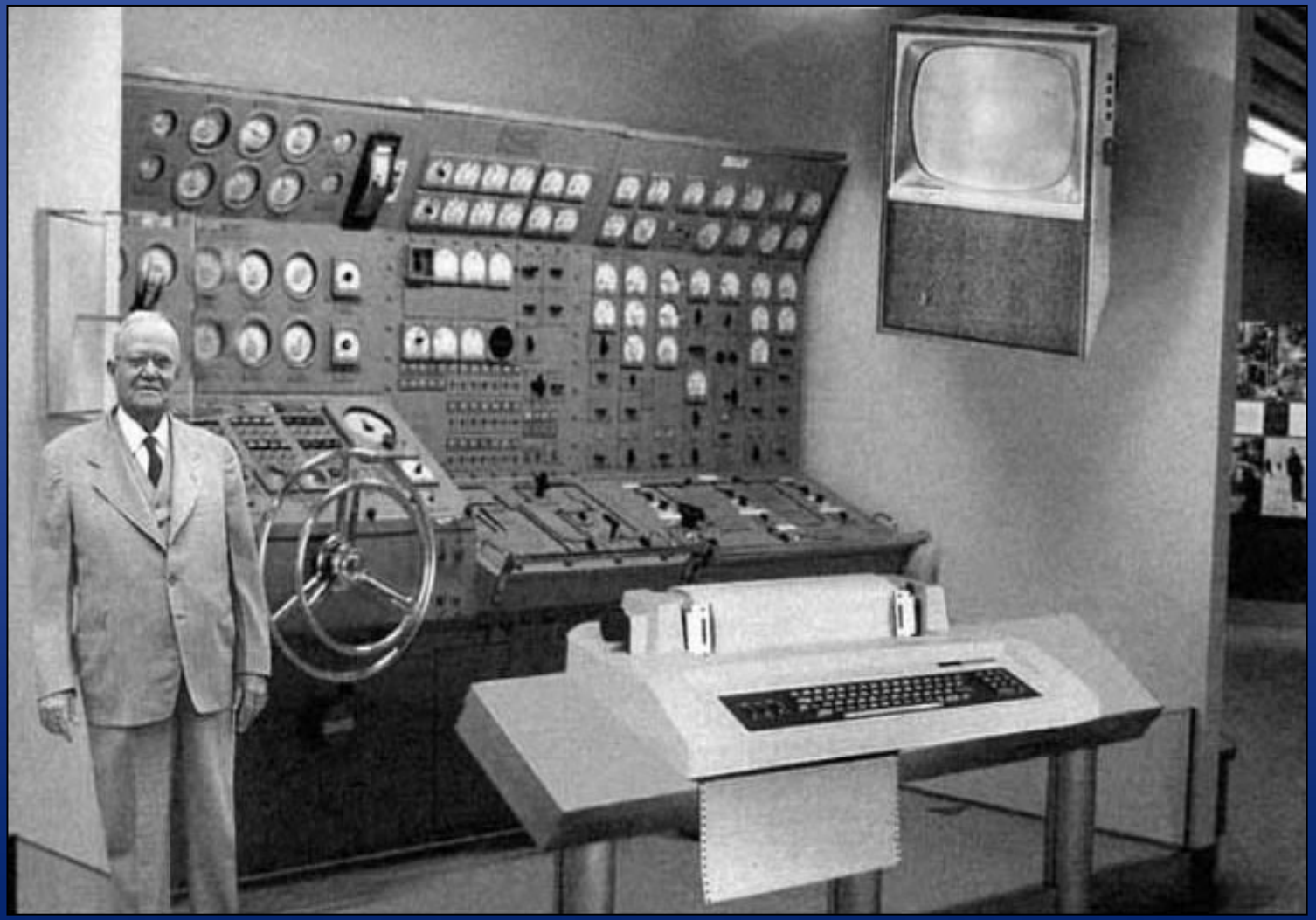
“Home Computers In 2004”



***Popular Science*, 1954**

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Safer and More Affordable
–
Clinical and Business Imperatives Aligned

Ed Weisbart, MD, CPE
Chief Medical Officer

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